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Development of a wireless distributed three-channel stimulator system used for automated triggering of stimulation to enable coordinated task execution in stroke patients

by
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Abstract

Each year, hundreds of thousands of people are affected by a neurological related disease or injury causing some of them partial or complete dysfunction of one or more limbs. Functional Electrical Stimulation (FES) techniques have shown a significant improvement in mobility and function for many of these people. FES is an artificial technique of stimulating motor nerves to cause contraction of muscles. Depending on the extent of the injury and the movement disorder, multiple channels of stimulation and sensors might be necessary. However, this results in a complex multi-channel stimulator which is often rejected by the user due to the size, complexity and cosmesis. These issues can be addressed to some extent by using distributed systems that split the complex function of the multi-channel stimulator into multiple local stimulators around the body. However, using conventional techniques will result in a complex network of wires making it difficult and inconvenient for the wearer. The obvious solution is to replace wires with a wireless network where each node from the network communicates with one or multiple nodes, and is small enough to be placed where needed. Because of the safety implications of this application, any wireless network of this type must be at least as reliable as a wired system with latencies that do not weaken the performance of the system. This research involves identifying the wireless technology that can ensure reliability, short latency and low power consumption in environments where FES is used. In addition, the research investigates a control strategy for a wireless distributed FES system which consists of three-channel stimulators and four sensors. This system is designed to correct drop foot and assist reciprocal arm swing in walking mode, and enables reaching and grasping stimulation when the user is stationary. This combination of a wireless network of stimulators and sensors allows the development of a new generation of FES systems that are convenient for use and which are expandable so that new sensors or stimulators can be easily added to the network to meet the needs of each individual user. The experimental results confirmed the feasibility of a wireless network of stimulators and sensors using ZigBee, and indicated that the control strategy was successful in enabling the required stimulation channels.

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Chapter 1 - Introduction

1.1 Background

Neurological diseases and injuries affect hundreds of thousands of people each year. Some of the causes are Stroke, Multiple Sclerosis (MS), head injuries, and incomplete spinal cord injuries. In England, at least 450,000 people are left with severe disabilities caused by Stroke [1]. An estimated 2,500,000 people in the world have MS [2]. Most common symptoms of these conditions are weakness or paralysis of one or multiple limbs, resulting in permanent disabilities in many cases. Functional Electrical Stimulation (FES) has been increasingly accepted as a treatment of such conditions. The National Institute for Health and Clinical Excellence (NICE) in the United Kingdom released in January 2009 a review of clinical evidence on electrical stimulation of the lower limb in which they recognised it as an effective treatment [3].

Functional electrical stimulation is an electrotherapy that involves artificially stimulating motor nerves to regain function in the paralysed muscle. Stimulation creates an action potential in the nerve which is conducted to a muscle group, causing contraction. FES is usually applied on skeletal muscles which results in functional movements of joints. It has been proven that FES helps reduce efforts in walking [3] and increases muscle strength [4]. This results in improvement of the mobility in the neurological patient and increases their independence in every day tasks.

The first practical use of FES was developed by Liberson [5] in 1961 who proposed stimulation of the common peroneal nerve to correct drop foot. Currently, drop foot stimulation is the most common application of FES [6]. Drop foot stimulators are single channel FES systems which stimulate the tibialis anterior muscle group periodically during walking. Nowadays, applications of FES are widened to include different neurological impairment and are used for upper and lower limb movement correction [7]. There are many commercial FES systems available at the present time which are mainly single or two channel stimulators [8].

Multi-channel stimulators can contribute to improve complicated neurological conditions that require stimulation of multiple muscle groups. For instance, a four-channel stimulator can improve walking of patients with paretic leg as suggested by Kojovic [9]. However, multi-channel stimulators suffer from some practical limitations in functional use. Some of these limitations are the bulkiness of these devices and the long wires between stimulator unit and sensors/electrodes.

One commonly used single channel FES system is the Odstock Drop Foot Stimulator (ODFS, Odstock Medical Limited, UK) used to correct drop foot. Taylor et al. discussed the patients' feedback on this device and highlighted the issues identified by users [10]. Their findings suggest that the system was causing difficulties for users due to its design. Some of the difficulties found by patients, according to this paper, were difficulties with dressing and undressing to use the toilet, and transferring to and from a car. This was caused by the long wires running from the waist, where the stimulator is commonly located, to the electrodes on the lower leg and to the sensor underneath the heel. These wires are subject to breakage and can be detached resulting in reliability issues. Moreover, wires were found to make the device less cosmetic than users would have wished.

As a result, multi-channel stimulators designed with the same concept are likely to be rejected by users for the same reasons. This is due to the fact that multi-channel stimulators have more wires and are inherently bulkier. Therefore, multi-channel stimulator design needs to be improved to increase the acceptability amongst patients and simplify the user interface. Removing wires or minimising their number might also improve the acceptance of users. This can be done either by using different types of sensors that can be placed in the stimulator unit, or replacing wires by a wireless network.

Based on these points, two research questions have been formulated, as explained in the following section.

1.2 Research questions

Question 1: *Is it possible to design an effective wireless FES system?*

This question covers an investigation of the feasibility of a wireless FES system that ensures reliable communication between stimulators and sensors.

Question 2: *Can a three-channel stimulator system be designed to automate triggering stimulation to enable coordinated task execution?*

This defines the main aim of this research which is to investigate a wireless distributed system of stimulators and sensors designed with an adaptive control philosophy, in order to use intelligently data from sensors to enable stimulation channels only when needed. This is verified by developing a wireless three-channel FES system for a specific application, which consists of drop foot and reciprocal arm swing stimulation when walking is detected, and reaching stimulation when stationary.

1.3 Research objectives

The first step of this research was to investigate the use of alternative sensors for drop foot stimulation which can replace the sensor commonly placed under the heel. The literature review included sensors that can be built in the stimulator which eliminates the need for a sensor lead. This is a solution for some of the problems found by drop foot stimulator users. However, this might not be enough to eliminate all problems since, as found in the literature, alternative sensors do not detect events accurately for all patients and do not match the performance of the pressure sensor. Therefore, another solution needs to be investigated which would be to replace wires with a wireless network. This requires integrating a wireless interface to both the heel switch and the stimulator. This wireless interface should not deteriorate the performance of the FES system compared to the current wired system.

Another benefit from using wireless networks is the ease of sharing data between multiple nodes in the network. This results in efficient use of sensory data by eliminating redundant sensors. In addition, it allows combining data from multiple sensors located in a variety of anatomical positions to improve the accuracy of event detection.

This research also investigated a control philosophy for a three-channel distributed FES system of stimulators and sensors. This application is for drop foot and reciprocal arm swing stimulation when the user is walking, and enables stimulation of reaching and grasping objects, if intention is detected, when the user is stationary. This requires the intelligent use of sensory data from multiple sensors to detect whether the user is walking or not, to enable the appropriate stimulation channels. The system also combines sensory data for accurate detection of events such as combining data from the

pressure sensor with an accelerometer to accurately determine if a heel event occurred when walking or if the user is transferring weight whilst standing. This control strategy and the intelligent use of sensors open the door for functional applications that assist coordinated movements, and automated activation of tasks. It also improves the comfort of using FES since it stops false positive stimulations, such as, drop foot stimulation caused by transferring weight from one side to the other whilst at rest.

1.4 Thesis outline

This document is arranged in 7 chapters including the literature search, the experiments and results, and conclusions.

Chapter 2 is a literature review on FES systems. It introduces the physiology of the nervous system and the natural control of movement, followed by how movements are affected by neurological damage or disease. The rest of the chapter explains FES and how it is used to regain some function in the paralysed muscle. It also reviews FES systems in terms of the sensors used for triggering and control systems, and their potential improvements in function.

Chapter 3 reviews wireless technologies that can be used in FES systems, and explains how wireless networks could benefit the FES user. The chapter describes the requirements for an effective wireless FES system, and compares the commercially available wireless technologies that can be used for FES systems. ZigBee networks are then explained.

Chapter 4 describes the experimental methodology of this research project. The first part describes the experiments designed to verify the wireless requirements needed for the wireless FES system. The second part of the chapter describes the experiments and prototype designed for the main application of this work to answer research question 2.

Chapter 5 reports results from the experiments described in chapter 4. This chapter is also arranged in two main parts; results of the experiments on a wireless drop foot stimulator followed by results of the experiments on the second prototype.

Chapter 6 discusses the results given in chapter 5.

Chapter 7 includes conclusions drown from this research project, and future work.

Chapter 2 - Nervous System Overview and Functional Electrical Stimulation

2.1 Introduction

Electrical Stimulation has been used for many centuries for medical treatment; it was first used to reduce pain such as headache and to stop haemorrhage. Electric shocks from Torpedo fish were first used, early in the 4th century, to relieve headache. The ancients also used static electricity generated by rubbing amber. In 1744, a German physician, Kratzenstein, described using static electricity to treat paralysis with one of his patients. The invention of the Leyden jar in 1745 broadened the use of electricity to treat disorders, such as, kidney stone, epilepsy and paralysis [11].

In 1791, Luigi Galvani discovered that applying dissimilar metals to a nerve resulted in contraction of a group of muscles. Few years later, in 1799, Alessandro Volta noted that applying a continuous current to a muscle resulted in contraction only with the first flow of electricity and sometimes when the current is cut. This was confirmed by experiments performed by Johann Wilhelm Ritter, who concluded that muscle contraction can only result from a stimulus applied with briskness [11].

The electromagnetic machine, developed by Michael Faraday in 1831, was used to generate alternated current known as 'faradic current' to medical practitioners. The use of this current as well as the galvanic current was diagnosed in 1840, which unveiled that, unlike galvanic current, faraday current does not cause contraction of paralysed muscles. It was also concluded that the duration of the current was deciding factor in causing contraction of muscles [11]. Following this, electrical stimulation was better understood in the latter half of the 19th century, and more work was achieved in therapeutic applications of electrical stimulation, such as using high frequency current to relieve pain of rheumatism and fractures.

In 1960, electrical stimulation was first suggested as a functional solution to correct drop foot by Liberson et al [5]. Stimulation is applied to the group of muscles responsible for dorsiflexion of the ankle (lifting the foot to decrease the angle between

the foot and the leg). Many efforts have been made to improve the use of Functional Electrical Stimulation and extend its applications to more complicated movements; such as applying stimulation on more than one paralysed muscle group of the body.

This chapter introduces the nervous system which controls voluntary movements and the effect of neurological diseases on patients. This is followed by an introduction to Functional Electrical Stimulation (FES) systems. The chapter then reviews sensors and control strategies of FES systems.

2.2 Nervous system

The nervous system is a highly complex and organised network of neurons. Some of its functions are sensation, coordinating movements, and thoughts. It is composed of two subdivisions; the Central Nervous System (CNS), and the Peripheral Nervous System (PNS) [12].

2.2.1 Central nervous system

The CNS consists of the brain and the spinal cord above T12. It is the part of the nervous system where thoughts, emotions, and memories are generated. It is also responsible for processing the incoming sensory information which is used to make decisions or initiate a response.

2.2.2 Peripheral nervous system

The PNS extends from the CNS to the limbs and the different organs in the body. It is responsible for conveying sensory information from all sensory receptors (such as touch, vision, and hearing) to the CNS and conducting nerve impulses (voluntary and involuntary) from the CNS to muscles.

2.3 Natural stimulus of movements

Voluntary and involuntary movements, such as moving limbs to perform a task, starts in the CNS which initiates a stimulus that is transferred to an Upper Motor Neuron (UMN). This causes an action potential in the UMN that travels down to the PNS. An action potential in nerves is a rapid change of the potential of the membrane of the neuron, which travels in the neuron from the location of stimulus to the other end of the neuron. When the stimulus reaches the PNS it is passed from the UMN to the Lower Motor Neuron (LMN). This causes an action potential in the LMN which travels down

to the muscle group, resulting in an action potential in the muscle, to which muscle fibres respond by contracting [12]. This mechanism is summarised in Figure 2.1.

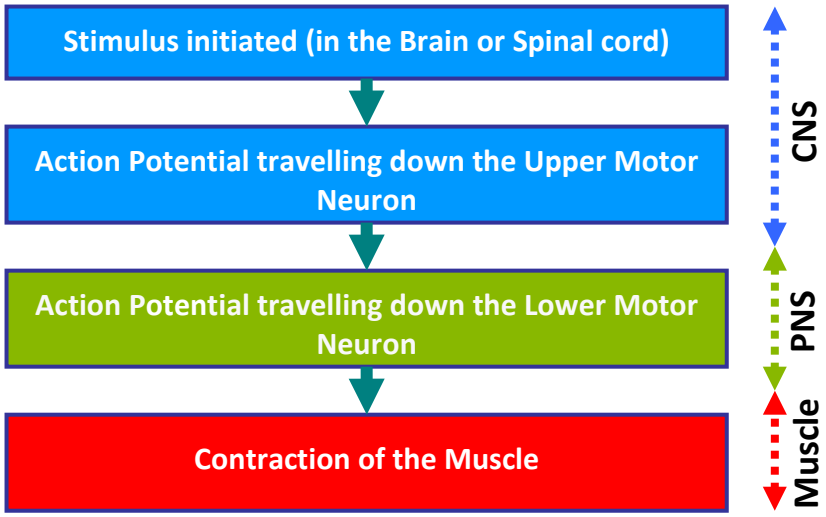


Figure 2.1: Diagram summarising the main stages in the nervous system causing a contraction of a muscle group

2.4 Neurological lesion

Neurological damage can affect the sensory and/or the motor neurons. Depending on which level of the nervous system is affected, it is classified as upper or lower lesion.

2.4.1 Lower motor neuron lesion

Lower motor neurons are part of the PNS. They conduct stimulus from the connection between CNS and PNS to muscles which causes a movement. These neurons can be damaged by a trauma, for instance, resulting in Lower Motor Neuron Lesion (LMNL). A neuron is a single cell which is not repairable. As a result, the damaged lower motor neuron is permanent and the consequence of this is paralysis of the muscle(s) controlled via this neuron. The muscle in this condition is called a denervated muscle.

A lower motor neuron lesion results in flaccid paralysis of the denervated muscle, which results in a decrease or loss of muscle tone. Muscle tone is the small amount of tension that keeps the muscle firm but not strong enough to cause movement. LMNL also causes loss of both voluntary and reflex movements. As a result, muscle bulk is lost gradually and the denervated muscle becomes limp [12].

2.4.2 Upper motor neuron lesion

An Upper Motor Neuron Lesion (UMNL) is damage to motor neurons in the CNS. This can be as a result of neurological diseases (such as stroke, Multiple Sclerosis (MS), cerebral palsy, and Parkinson's disease), head injury, or spinal cord injury above T12 (damage to the CNS). Depending on the extent and location of the neurological damage, the patient can suffer from weak or even complete loss of function in the muscles linked via the damaged neurons. The most common neurological disease is stroke which is the cause of severe disabilities. In England, 450,000 people are living with disabilities resulting from stroke [1]. Stroke is a result of a lack or insufficient supply of oxygen and nutrients to an area of the brain caused by a clot or blood vessel burst.

Some patients with UMNL suffer from motor dysfunction in one or multiple limbs. Although the lower motor neurons are intact, the stimulus does not reach the muscle since it is either not created (damage to the area normally generating the stimulus) or not transmitted due to damage in the link. An upper motor neuron lesion is associated with spastic paralysis, which causes an increase in muscle tone and exaggerated reflex in skeletal muscles. This results in stiffness which increases the difficulty of movement. This is explained in more details in [12].

On the other hand, Muscles in this condition can still respond to an impulse from the lower motor neuron, although the upper motor neurons are damaged. Therefore, if a lower motor neuron can be stimulated to conduct an action potential to the muscle, the muscle will respond by contracting [11]. This introduces the next section which explains artificial stimulation of motor nerves.

2.5 Electrical stimulation

Electrical stimulation is an artificial technique to cause contraction of one or multiple muscle groups. Electrical stimulation is usually applied to the lower motor neuron and can be applied directly to the muscle or to the peripheral nerve supplying that muscle. The electric current used to stimulate must be a pulse wave, which is characterised by an off period, required to cause an action potential. Nerve stimulation requires a current intensity up to 120mA [8] and pulse width up to 300μs [11]. On the other hand, denervated muscle stimulation requires much higher current intensity and pulse width; up to 250mA intensity and up to 300ms pulse width [13, 14]. This could harm the skin if small electrodes are used [13], caused by the high current density concentrated on a

small area of the skin. Figure 2.2 shows the difference between nerve stimulation and muscle stimulation in terms of current intensity and pulse width. Due to the high levels of stimulation required in muscle stimulation, muscle stimulation is only used to stimulate denervated muscles, since it is the only way of causing a contraction as explained in the previous section. Therefore, this work will consider nerve stimulation on subjects with intact lower motor neuron only.

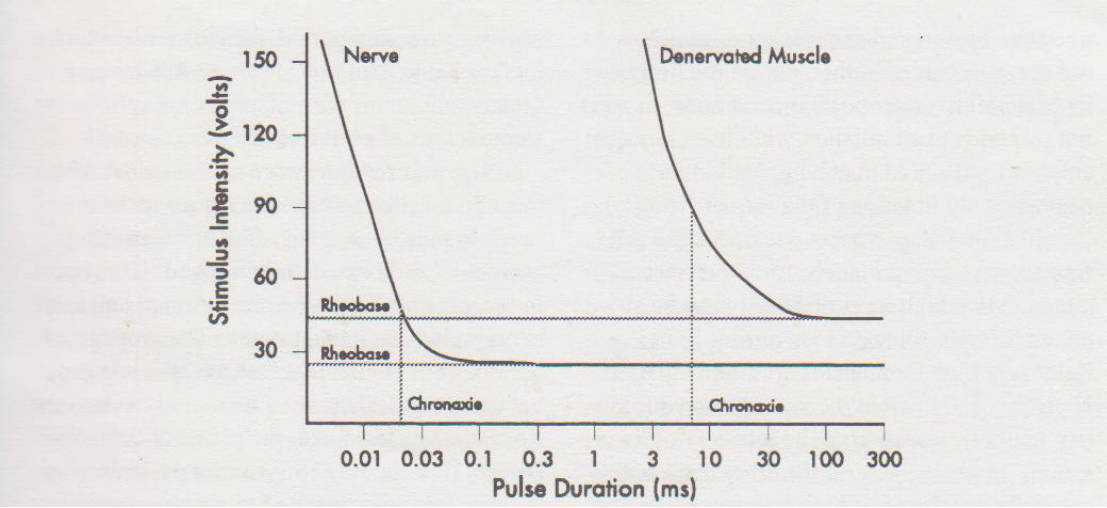


Figure 2.2: Current intensity versus current pulse width required to cause an action potential in nerves and muscles (from [11])

Nerve stimulation can be applied only when the lower motor nerve is intact. This type of stimulation is applied by two main techniques; surface stimulation or implanted stimulation. Surface stimulation is the most common since it does not require surgery and can be rapidly set up. Two electrodes are needed in surface stimulation, placed on the skin proximate to the targeted nerve as illustrated in Figure 2.3. The electrodes apply an electric field underneath the skin which causes depolarisation of the membrane in neurons resulting in an action potential. The action potential travels in both direction in the neurons, and eventually, it reaches the targeted muscle in one end. As a result, muscle fibres contract [11].

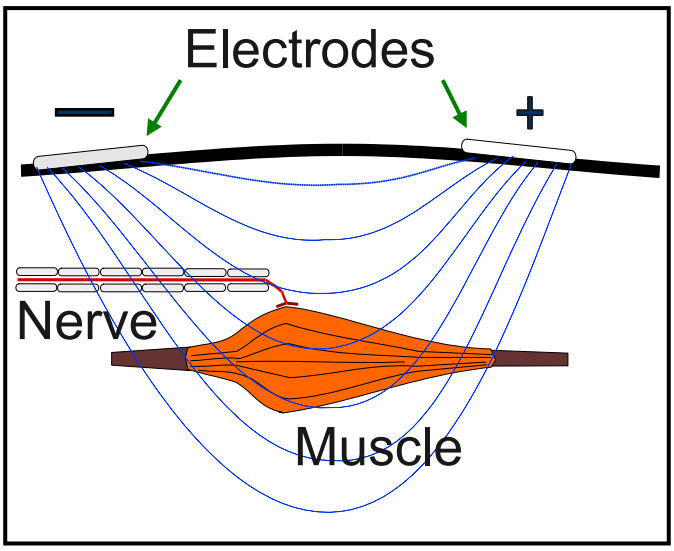


Figure 2.3: Electrical Stimulation principle [15]

Implanted stimulation requires surgical intervention in order to implant electrodes attached directly around the targeted nerve. This has the advantage of permanent accurate targeting of the nerve and no need to reposition electrodes to achieve a good response. This is not the case in surface stimulation, in which, some surface stimulation users find it difficult to position electrodes as described by Taylor et al. [10]. However, surface stimulation is preferable, especially for research, as it does not require surgery and can be applied rapidly. Therefore, the prototypes developed for this project were chosen to use surface stimulation.

2.6 FES systems

Functional Electrical Stimulation (FES) is a technique of stimulating artificially a function in the human body. FES has a wide range of uses nowadays, such as, pacemakers, limb movement, bladder and bowel control, deep brain stimulation, pain relief, and treatment of facial palsy [16]. The use of FES for limb movement is still not widely used clinically due to impracticality in some cases. This work therefore concentrates on the use of FES for limb movement.

Functional Electrical Stimulation (FES) systems for limb movement are often used on a daily basis to assist and correct impairment of movement caused by some neurological dysfunctions [17]. This can only be applied for patients with intact lower motor neurone as explained earlier.

The first clinical application of FES was the drop foot system suggested by Liberson [5] in 1961. Following this, many improvements have been made in FES in the last 50 years, especially with the arrival of microcontrollers [6]. Other applications of FES have been developed over the years including both lower and upper limb stimulation. However, many of these applications are not widely used clinically. In addition, most of the research covers lower limb FES systems [17]. This is reflected in the commercial surface FES devices available currently which are mainly for lower limb such as the ODFS Pace (OML, UK), NESS L300 (Bioness, USA), and the WalkAide (Innovative Neurotronics, USA) [6,8], although there are some commercial upper limb FES systems such as the NESS H200 (Bioness, USA) [8,17].

In 1997, Burridge et al. [18] published a randomised controlled trial to measure the effect of drop foot stimulation on the effort and walking speed, which revealed that this device has a clinical benefit as an orthosis. This was the first evaluation of an FES system for clinical use [16]. Nowadays, FES systems are recommended by the National Institute of Clinical Excellence (NICE) [3] and the Royal College of Physicians of London [19].

Generally, FES systems are composed of one or more stimulation channels (where each stimulation channel stimulates one group of muscles), one or multiple sensors, and a control unit to adjust the stimulation parameters and generate the output. Multi-channel stimulation is used when activation of more than one muscle group is required in order to achieve complex movements, such as the four channel stimulator discussed in [9], where stimulation is applied on four different muscle groups (Hamstring, Quadriceps, Tibialis anterior, and Soleus) to improve walking in stroke patients, allowing controlled motion in the ankle and knee joints.

This project considered combining an upper limb and a lower limb use of FES, in order to develop a system that consists of multiple stimulation channels and multiple sensors that can enable channels to work co-ordinately or independently, depending on the need. Therefore, the chosen applications were drop foot stimulation, reciprocal arm swing stimulation, and reaching stimulation. The first two applications are coordinated and the latter is enabled only when the first two are not needed. This therefore requires a system that can adapt to the conditions of use, using multiple sensors. The following sections explain these three FES applications.

2.6.1 Drop foot stimulation

The most common application of FES is drop foot stimulation which is a single channel stimulation to correct the inability to dorsiflex the foot (lifting the foot and decreasing the angle between the foot and the leg. See Figure 2.4 - a), and insufficient eversion (ankle turning outwards as shown in Figure 2.4 - b). It has been reported by Burridge et al [18] and Kottink et al [20] that drop foot FES systems improve the efficiency of the pathological gait and reduce the risk of falling.

(a) Dorsiflexion (b) Eversion

Figure 2.4: Movements at ankle joint [12]

Stimulation is applied to the motor nerve, the common peroneal nerve, controlling the group of muscles responsible for dorsiflexion and eversion to generate the wanted movement. The foot is dorsiflexed and everted only during the swing phase to clear it from the ground, and at the start of the stance phase. This is to stabilise the foot before it is flat on the floor. The summary of drop foot stimulation activation is shown in Figure 2.5. Therefore, detecting the start and finish of both phases is needed for this application.

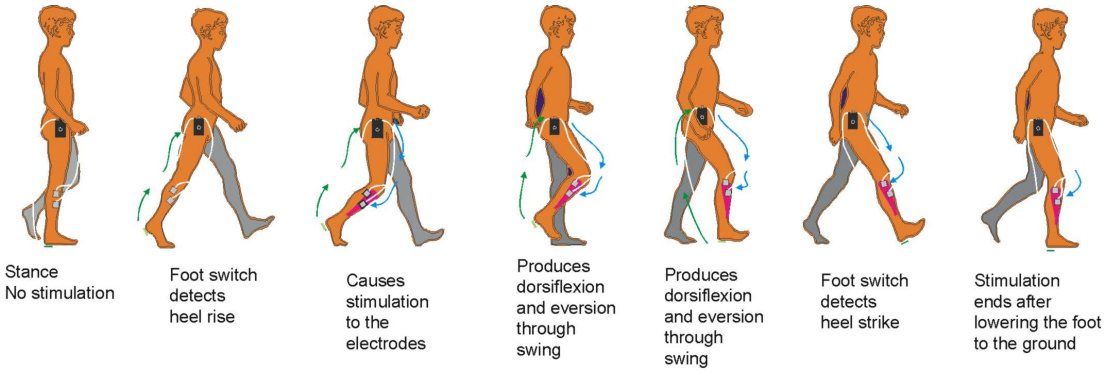


Figure 2.5: Diagram of gait cycle with drop foot stimulation [21]

Swing phase is the period of time when the foot is lifted from the ground. It starts with the toe off the ground and finishes just before the heel makes contact with the ground

(heel strike). Stance phase is the rest of the gait cycle which is while the foot is making contact with the ground (from heel strike to toe off).

There are many techniques for detecting both swing and stance phases [22]. For drop foot system such as the ODFS Pace (OML, UK), the start and finish of the period of stimulation is commonly defined as the phase between the moment the heel of the stimulated leg is lifted (heel rise) and the moment the heel touches the floor again (heel strike) [8].

2.6.2 Reciprocal arm swing stimulation

Reciprocal arm swing can be achieved by stimulation of the triceps brachii muscle during swing phase of the foot on the same side [23]. This application is not widely researched and used, as not many publications have been found in the literature. Most work have been concentrated on lower limbs although natural walking involves upper limbs as well as lower limbs [24]. As explained by Rebersek [25], reciprocal arm swing has benefits to the step length and push-off velocity for the hemiplegic. Moreover, Umberger et al [26] suggest that suppressing arm swing is predicted to increase the gross metabolic cost of walking by up to 15% on unimpaired subjects. Therefore, reciprocal arm swing can prevent the increase of the gross metabolic cost of walking for patients with upper limb impairment. This application therefore is included in this research as part of the proposed three-channel system.

2.6.3 Reaching and grasping stimulation

Reaching systems or hand opening stimulation enables the user suffering from an upper limb impairment to reach and grasp objects. This involves stimulation of the elbow extensors (triceps brachii) and hand/fingers extensors muscles. It has been suggested that patients would benefit from a functional use of such stimulation by triggering it voluntarily [27,28]. Moreover it can have long term benefit as explained by De Kroon et al. [29]. Voluntary triggering is achieved by detection of the intension of the user to reach. This is usually done by monitoring the tilting angle of the arm when moving forward. Prochazka et al [30] and Popovic et al. [31] proposed a bionic glove for grasping stimulation for patients with spinal cord injury. Their results suggest that the proposed system can significantly improve grasping force and increase independence for these patients.

This application can be more effective if only enabled when the user is intending to reach, and avoid false positive triggers when the patient is walking and swinging the arm. Therefore, a system that can detect whether the user is walking or not will have an advantage over the systems proposed in [27,32]. This is due to the fact that reaching and grasping are usually intended when standing or sitting. This work will investigate integrating reaching and grasping stimulation in the proposed system with ability to detect walking to disable this application automatically.

Reliable event detection is crucial for an effective FES system, therefore sensor technology and detection algorithms have to be designed carefully to achieve maximum reliability. The following section compares the main sensor technologies currently used in FES systems.

2.7 Triggering sensors for FES systems

Sensors can be used to detect events that are trigger the start and finish of stimulation in FES systems. A variety of sensor technologies are used in FES systems. Depending on the application, some sensor technologies perform better than others. Data from sensors is usually processed by a detection algorithm. The most common technique in commercial products used for lower limb (Odstock Stimulator, NESS L300, and the Duo-STIM) is using a footswitch placed under the heel. The upper limb is usually triggered using kinematic sensors such as [32]. Other techniques are used in FES including hand switch [33] and electromyography (EMG) [34]. A discussion of sensors used to trigger lower limb stimulation was presented by the author at a conference [35] (appendix K).

2.7.1 Hand switch

The simplest approach is to use a hand switch to trigger stimulation as described by Kralj et al. [33] and Tomovi [36]. The advantage of this technique is the complete control that the user has over stimulation timing and adaptability to their needs and comfort. Ott et al. [37] suggested that a hand switch performs better than a Force-Sensing Resistor (FSR) (FSR will be explained in the next section) for drop foot patients in terms of reliability of triggering the stimulation. However, this imposes a conscious burden of pressing the switch at the right time. This could result in the rejection of the system due to the amount of concentration required to operate the

system as mentioned by Franken et al. [38] and by Williamson et al. [39]. Moreover, FSRs have been improved since [37] was published.

Fisekovic et al. [40] compared a hand controlled multi-channel walking FES system with a proposed automatic control of a multi-channel walking FES system. Their results showed that the automated control performs better than the hand controlled system. They reported that the walking speed for a hand controlled system was 16.7m/min, and the walking speed for the automated control system was 41m/min. this shows a significant improvement in walking speed for the second method. Popovic et al. [41] compared a hand switch control walking system to three methods of automatic controlled systems for paraplegics. They found that the automatic control systems are less energy demanding on the user than the hand controlled one. Moreover, patients' feedback in this study showed that five out of six preferred one of the automatic modes. This could be explained by the fact that hand-switch controlled stimulation requires extra concentration.

A hand switch can also be used for upper limb, such as triggering reaching and grasping sequence in the NESS H200 (Bioness, USA). However, this requires using a functioning hand which would be the one on the other side for the patient with hemiplegia. This can restrict the use of both hands at the same time.

2.7.2 Footswitch

Footswitches are commonly Force-Sensing Resistors (FSR). They are characterised by the simplicity of the output signal which is in an On/Off format resulting in simple detection algorithms. FSRs change resistance relative to the applied pressure, therefore, when used in a voltage divider circuit, the voltage across the FSR changes depending on the pressure applied. As a result, any significant change of the voltage is interpreted as heel rise or heel strike when the FSR is placed under the heel. Figure 2.6 represents a sample data of FSR voltage, recorded by the author, while pressed and released periodically, and resulting stimulation trigger. This graph was generated using spread sheet software (Microsoft Excel) which calculated the stimulation trigger based on the FSR signal. The stimulation triggering signal toggles between two logic levels; high for stimulation on, and low for stimulation off.

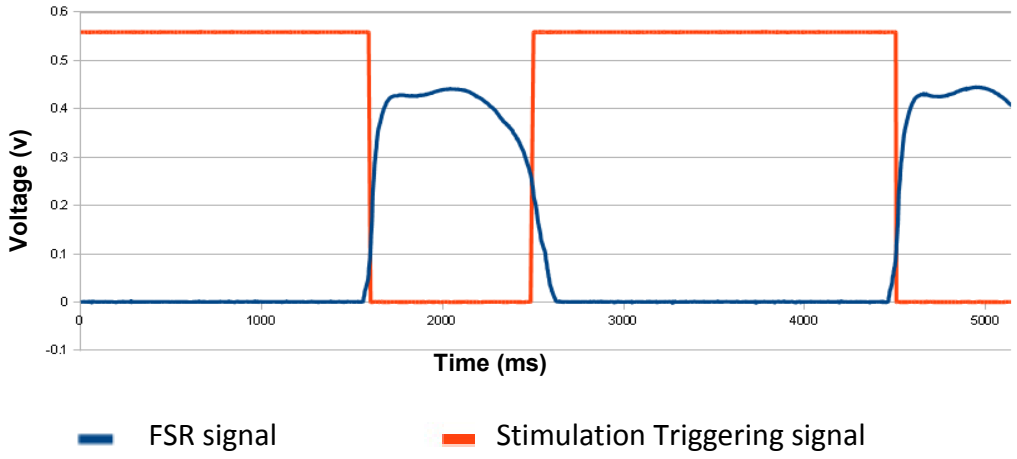


Figure 2.6: Sample of FSR voltage and stimulation trigger signals

Footswitches are suitable for stimulation channels triggered on heel rise and heel strike (drop foot for example), or toe contact and toe off (the footswitch placed under the toe). However, this is limited to stimulation of muscle groups that are activated/deactivated when one of the two heel events or the two toe events occurs. Other applications of FES for walking require muscle activation/deactivation at timings that do not coincide with these four events of the gait cycle. These stimulation channels therefore can only be activated/deactivated after a delay from one of these four events if relying on an FSR. For instance, calf muscle stimulation (used to improve the push off in walking and which occurs before the swing phase) is triggered after a delay from heel strike, since push off occurs naturally just before heel rise. Triggering on heel rise will not be effective as explained by Monaghan et al. [42] who investigated a push off stimulator. Preset fixed delays for triggering stimulation might not be optimal due to the variation of gait events with walking speed. So the effectiveness of the system will depend on walking speed [43,44].

There has been some reports, in the literature, of low reliability in detecting gait events using footswitches as claimed by Jasiewicz et al. [45], Willemsen et al. [46], and Mansfield et al. [47]. Low reliability of footswitches could be the result of movement of the foot in the shoe during the swing phase as reported by Monaghan et al. [42], or due to the posture of the foot when it lands on the ground. For instance, a footswitch placed under the heel will not detect heel events reliably on toe walker subjects due to the lack of pressure from the heel. Moreover, shuffling and transferring weight from one leg to the other causes mis-triggering which affects reliability. On the other hand, Hanlon et al.

[48] reported no reliability issues with footswitches and recommended them over accelerometers due to the accuracy of detecting initial foot contact. These two different findings might be explained by the fact that detection algorithms used by the mentioned researchers as well as the FSR technology used are different. In addition, some recent improvements in processing power meant a better detection algorithms can be implemented. For instance, the algorithms can be designed to overcome some of the problems found by some researchers such as double bouncing after heel strike.

Footswitches have the disadvantage of requiring the user to wear shoes as explained by Dai et al. [49]. Moreover, footswitches could wear quickly as reported by Monaghan et al. [43], however this depends on the quality of materials used in their construction. Modern footswitches are built with better quality and can last longer. Hence, current commercial FES systems, such as the ODFS Pace (OML, UK) and the NESS L300 (Bioness, USA), trigger stimulation using a footswitch.

2.7.3 Kinematic sensors

Overcoming some of the problems encountered with footswitches could be achieved using sensors that measure the angle of joints or the orientation of limb segments. This can enable detection of gait events in more details such as the start, middle, and end of swing phase which can not be identified using a footswitch. Kinematic sensors have the potential to be used to measure joint angles based on acceleration if using accelerometers or on angular velocity if using gyroscopes.

One or multiple kinematic sensors can be used for the detection of gait events. Dai et al. [49] proposed a system with a single accelerometer used as a tilt sensor placed on the shank. Data from a single accelerometer can be affected by noise due to the walking pattern. For instance, heel strike generates noticeable vibrations (noise), which affects the tilting estimation. The acceleration data therefore has to be filtered using a Low Pass Filter (LPF), as explained by Veltink et al. [50]. The filtered data represents tilt information of the shank which is used to detect heel rise and heel strike. However, Cikajlo et al. [51] explained that the required LPF should have a 3Hz cut off frequency and a steep slope, meaning the use of a high order filter that might result in an unacceptable high latency. Foglyano et al. [52] suggested using a three axis accelerometer built in with the stimulator attached to the waist. The accelerometer was used to detect heel strike on both sides to trigger stimulation of hip flexion and

dorsiflexion (drop foot stimulation). The system was estimated accurate when tested on one stroke patient with hemiplegia. The initial results of this case study are promising but further investigation is required on more subjects. For applications that require detection of heel rise, a delay from heel strike could be used to predict heel rise. However, this is not as accurate as detecting the actual event since the prediction could be affected by walking speed. Therefore, FSRs are more suitable for FES applications that require detection of both heel rise and heel strike.

Cikajlo et al. [51] proposed using a gyroscope as the main source of angle data and combined it with the data from an accelerometer after applying a Kalman filter. This was suggested, to overcome the technical issues when using a single accelerometer and to increase reliability. Ghoussayni et al. [53] proposed the use of a single gyroscope placed on the foot to trigger a drop foot FES system. Their experiments showed 96% accuracy of the system in detection of heel events on unimpaired subjects and 94% accuracy on impaired subjects (patients with drop foot). They also found that the accuracy of the footswitch they compared with slightly lower (95% for unimpaired and 91% for impaired).

Monaghan et al. [42] used a single gyroscope to detect heel events. The gyroscope was placed in a convenient location on the shank so that it could be integrated in the stimulator box used for drop foot. This eliminates the need for a wire from the sensor to the stimulator box. This system is reported to be independent of walking speed and foot contact method, and flexible in terms of the location on the shank. On the other hand, the detection algorithm requires high amplitude of velocity in swing followed by null velocity to perform reliably. Monaghan et al [42] reported that the system was good enough to be used reliably in detection of heel events on patients. In contrast to this, Cikajlo et al. [51] and Farrenkopf [54] stated that gyroscopes are liable to errors caused by changes in temperature and noise. In addition to this, they suffer from drift due to the fact that data is integrated to estimate joint angle, so an initial angle value is required. Using another kinematic sensor or an FSR will resolve these issues as suggested by Tong et al. [55]. Their proposed system resets at every step using a footswitch to solve the problem of drift while the person is walking and changing direction.

Mayagoitia et al. [56] proposed another method of solving the problem of drift in gyroscopes. This method consists of using two accelerometer mounted perpendicularly to each other to measure the initial angle in static conditions (when the only components

are gravity), which will be used as the initial angle. The two accelerometers can be built in the stimulator, attached to the lower leg, which is an advantage over the footswitch that requires a lead. However, they found that the proposed system is accurate as long as the walking speed is not high, because of the high vibrations when walking fast.

Gyroscopes can also be integrated with a footswitch controlled FES system to be used as a secondary sensor to avoid false positive triggering due to shifting weight from one leg to another, as proposed by Pappas et al. [57]. This system showed consistent high reliability in patients at different temperatures and walking speeds (99% reliability on uneven terrain and 96% reliable on stairs).

Using multiple gyroscopes and accelerometers on the leg will give high accuracy of the gait events according to Lau et al. [58]. They placed a gyroscope and an accelerometer on the foot, the shank, and the thigh. The system they proposed can be used for gait analysis as a replacement for optical motion analysis systems, which are costly and are not portable. Comparison of the two systems showed very close performances only if, the location where sensors are attached, and the configuration of sensors are optimised individually to each subject. Other research has been done on gait analysis systems using kinematic sensors as well [59,60] showing similar results as Lau et al. [58]. The issue with such systems is that data processing can not be implemented on a real time system. Moreover, timing accuracy of gait events detection of these systems is less than systems based on footswitches [48].

According to Miller [61], Kinematic sensors are characterised by low performance in pathological gait when manual detection rules are applied. Miller suggests using machine learning techniques to learn gait patterns of a number of impaired subjects to improve the accuracy of choosing detection rules. Once the system is trained, it can detect gait events accurately even on pathological gait, and the more gait patterns it is trained on the more accurate the system will be. This paper did not mention possible real time application to be used to trigger an FES system. Shimada et al. [62] also reported low performances of kinematic sensors using manual detection rules and proposed using a machine learning technique (Artificial Neural Network) to improve the reliability and accuracy of timing on stroke patients. Williamson et al. [39] compared two machine learning techniques, Rough Sets (RS) and Adaptive Logic Networks (ALN), using accelerometers. RS is an inductive learning method that generates rules to map input variables to output sets (see [63] for more details). Their

findings showed that both techniques are reliable in gait event detection on the three unimpaired subjects who took part in their study. They pointed that ALN has higher timing accuracy with a cost of heavier processing than RS (89% accuracy in RS and 93% accuracy in ALN).

Kinematic sensors have significant potential in triggering walking aid FES systems; however, reliability and timing accuracy, according to most papers reviewed, is less than footswitches especially for pathological gaits. Combining these types of sensors with footswitches can result in higher reliability and accuracy as explained by Pappas et al.[57]. Machine learning techniques to calculate detection rules can also be employed to improve reliability and timing accuracy for gait event detection [39].

Upper limb stimulation can be triggered using kinematic sensors such as the work described by Mann et al. [32]. This type of application relies on detection of events that do not correlate with gait cycle, for example, when the arm is reaching forward. The stimulator system described by Mann et al. [32] included an internal accelerometer, and was attached on the upper arm. The accelerometer was used as a tilt sensor, i.e. uses the gravity to estimate if the upper arm is tilted forward. This approach is characterised by a relatively simple detection algorithm. However, it could be affected by acceleration of the arm when moving forward or backwards.

Tresadern et al. [64] investigated using a learning machine technique, Artificial Neural Network (ANN), to estimate reaching cycle from acceleration data of the forearm. The acceleration data was obtained from motion capture of two stroke patients. The ANN algorithm was implemented and run in Matlab. The results suggested that this method was 80 to 90% accurate.

A motion sensing network of sensors was described by Tong et al. [65] and used to detect movements of the upper arm. Four sets of one accelerometer and one gyroscope were placed in: shoulder, upper arm, forearm, and back of the hand. This approach investigated using a sudden movement forward and backward to trigger hand grasp stimulation. The accelerometers on the shoulder and upper arm were more accurate in detecting the defined sudden movement than the gyroscopes. In the forearm and the hand, the gyroscopes were more accurate.

Chan et al. [66] developed a FES system for upper limb training with voluntary triggering of stimulation. Triggering was achieved using an accelerometer attached to

the finger on the contralateral hand. Depending on the flexion/extension of the finger, the stimulation is activated/deactivated to open the hand or not. This approach is similar to using a button since it relies on the unimpaired hand to voluntary activate or deactivate stimulation.

2.7.4 Electromyography (EMG)

Electromyography (EMG) is capturing the electric activity generated by the contraction of muscles. The levels of electric signals captured by EMG are relatively low which requires the use of an amplification stage. This raises the issue of noise which could affect the usability of the data. EMG can be used to trigger FES systems as suggested by Graupe et al. [67]. They used the EMG signal of the pectoralis muscles to trigger stimulation of a neuro-prosthesis for walking. The proposed system was effective and gave the user complete control. However this system did not give any feedback on the gait phases. EMG can be used to trigger stimulation for paraplegics who do not have any voluntary movements making footswitches and kinematic sensors unsuitable to trigger stimulation. Dutta et al. [68] proposed a FES system for patients with incomplete spinal cord injuries triggered with EMG signal. The system has proven to have potential to be effective for such conditions.

Peckham et al. [17] described the second-generation of the Freehand system, developed at Case Western Reserve University and the Cleveland VA Medical Center, which uses EMG of the muscles remaining under voluntary control as one approach to control the hand opening stimulation for C5 and C6 tetraplegics. This system was given to three patients in this configuration, i.e. EMG driven, and the results indicated “high level of satisfaction”.

2.7.5 Other techniques

Upshaw et al. [69] investigated using the natural sensory feedback from the foot to detect heel events. The system consists of implanting a nerve-cuff electrode around the calcaneal nerve (a branch of the tibial nerve) that carries sensory information from the natural pressure and touch sensory ends in the heel. The captured signal shows electrical activity in the nerve on every heel rise or heel strike. This raised the issue of differentiating which event is occurring; moreover the levels of the captured signal are very low compared to EMG signals of surrounding muscles causing significant interference according to Upshaw et al. [69].

Prochazka et al. [30] suggested a bionic glove that detects voluntary wrist movements to trigger stimulation either to open the hand or produce hand grasp. The sensor used in this glove is an inductive linear variable displacement transducer placed on the forearm. The moving part of the sensor is attached to the hand via a cable. This therefore allows the sensor to monitor the wrist angle to enable or disable stimulation. This requires voluntary control of the wrist joint in order to use this type of sensor. Prochazka et al. found that the bionic glove improved the force of grasping during evaluation of this device on nine spinal cord injured subjects. This reflects the good performance of the sensor in measuring the joint angle.

The Freehand system, described by Peckham et al. [17], can be configured to be controlled via a transducer for hand opening stimulation. In the first generation of this system the transducer was put externally on the contralateral shoulder. In the second generation, the joint angle transducer was implanted to detect wrist movements. Four patients were given the system, allowing them to grasp and release objects. The results were described as “satisfying”.

2.8 Control of FES systems

FES control systems range from simple open loop user-controlled systems to complex closed loop controllers [70]. Control of FES systems should be designed to be effective with a simple user interface that gives the user enough control without being too complicated. The following will introduce the most used control techniques in FES systems.

2.8.1 Open loop FES systems

The simplest control approach is an open loop control in which stimulation is triggered regardless of the muscle response. In such systems stimulation can be timed using a trigger or preset timings (the latter usually used in training stimulators). Stimulation parameters, such as stimulation levels and ramps, are usually adjusted manually. Ott et al. [71] designed an open loop system used for drop foot in which the user triggers stimulation using a hand switch. The control system in this case simply applies stimulation, as set manually, when it is triggered.

The most common open loop control method is triggered cycle open loop, which applies the same stimulation pattern periodically. Periods are determined usually using

sensors which detect identifiable repeatable events that determine the start and end of each period. For example, heel rise and heel strike mark the start and end of stimulation period in the drop foot FES [46,57,62,72].

This type of control system does not adapt to any changes that require modifying the stimulation parameters; muscle fatigue for instance. Stimulation parameters are usually preset by a clinician and not accessible by users except for stimulation level. Therefore, in some conditions the FES system could be ineffective by not adapting automatically to new conditions. Granat et al. [73] observed these effects as users of FES walking system experienced decrease in hip flexion response over time. However, this can be overcome by training the user on how to adjust stimulation levels to adapt it to the need and compensate for the effects of muscle fatigue.

Furthermore, the environment where the FES walking systems are used can change which requires changing the stimulation parameters. For instance, the user can be walking on a flat/uneven surface, going up/down hill, or climbing/descending stairs. These changes might affect the effectiveness of the system if stimulation parameters are not adapted to these conditions. So a control system that responds to changes in conditions, by applying suitable stimulation output, would improve the performance of FES systems and benefit users. This requires using sensors that can detect the events that necessitate changing stimulation parameters.

2.8.2 Closed loop FES systems

Closed loop FES systems use extra sensors to feedback the response of the stimulated muscles, this includes measuring joint angles and generated forces. This information is then used to modify the stimulation parameters. There are different methods used for this purpose and some of them are discussed in [74-76]. The feedback allows the control system to adjust, dynamically, stimulation parameters to achieve the wanted force or joint angle. This method allows the system to overcome fatigue. These systems could also be designed to track a trajectory for more complex applications such as the system described by Nahrstaedt et al. [75]. This system measures the angle of the ankle joint to track a predefined trajectory and iteratively learn the ideal stimulation pattern to achieve the wanted trajectory.

On the other hand, closed loop control would result in more complex control systems since more processing power is needed compared to open loop systems. Moreover,

additional sensors are needed which is not wanted by users who want FES systems to be as simple as possible with as few elements as possible, as explained in the following section. In addition, muscle response to stimulation is not linear which makes such control even more complex to design, as mentioned by Lynch et al. [77], and subject to instability. As a result, there are no closed loop commercial systems at present.

2.9 Potential improvements to FES systems

Taylor et al. published results of a survey on patients' perception of the Odstock Drop Foot Stimulator (ODFS) [78]. The ODFS III was a commercial stimulator used to assist walking, now replaced by the ODFS Pace. Hundred and sixty users (including 53 past users) responded to the survey. The outcome was that 16.9% of the participants stopped using the device because they found the device too difficult to use. Another 16.9% stopped because they found it unreliable. Moreover, the survey found that 3.8% of patients stopped using the ODFS because it was cosmetically unacceptable. In another survey on the same device involving 211 users, Taylor et al. [10] suggested that 48% of stroke patients using the device and 20% of MS patients found wearing it made dressing more difficult, and 27% of stroke patients and 20% of MS patients found difficulties dressing and undressing for the toilet while wearing the device. Transferring to and from a car was found difficult by 27% of stroke patients and 20% of MS users.

Dai et al. reported that wires in drop foot FES systems are subject to breakage and can be unplugged while the system is being used [49]. This was also reported by clinicians in the National Clinical FES Centre (Salisbury District Hospital, Salisbury, UK) that all patients are likely to experience, at least once whilst using the drop foot stimulator, footswitch lead becoming detached (unpublished data). For instance, when transferring to and from a car as reported in [10]. This happens due to either worn connectors or stressed wires after standing up. As a result, the device does not trigger stimulation which usually is not noticed by patients until they walk few steps. This might explain some of the reliability issues found with the ODFS III.

Multi-channel stimulators designed in the same concept would be subject to even more problems and would cause more difficulties for users compared to the reviewed ODFS. This is due to the fact that they include more wires and usually they are larger in size.

These findings support the fact that stimulators need to be improved in terms of user interface, reliability, and cosmesis. This is supported by the findings in [8] in which

they reported that “overly complicated user interfaces and large, bulky designs can deter patients from using the device on a day to day basis”. They also suggest that “wired sensors would also certainly hinder patient acceptance”. The solution is to use sensors that can be incorporated with stimulators or using a wireless link. The stimulators can also be designed to be worn where stimulation is needed (for example, drop foot FES on the lower leg), thus minimising the length of wires to the electrodes. However, this could result in difficulties controlling the stimulator (pausing/unpausing the device and adjusting the stimulation level) for patients with weak movements in their upper limbs (often the case with stroke patients) since they will find it unreachable. Therefore, for these patients, a remote control could be designed to control the system wirelessly, which would further improve the usability.

Multi-channel FES systems can be designed to detect changes in conditions or situations in which either some stimulation channels are not needed or additional stimulation channels are required. For instance, some channels can be activated when walking (drop foot and reciprocal arm swing), and other channels can be enabled when the user is not walking (two channel reaching and grasping stimulation). In the mentioned example, one of the stimulation channels is common for both modes. However, stimulation in this channel is triggered by a different input in each mode. In walking mode it is triggered by gait (heel) events, and triggered by reaching attempt detection in the other mode.

This work, therefore, investigates a new concept of multi-channel FES systems which takes in consideration the arguments mentioned above in terms of usability and convenience. It consists of a three-channel stimulator for drop foot and reciprocal arm swing in walking mode, and reaching and grasping in standing/sitting mode. Following the findings in the review of sensors, the drop foot and reciprocal arm swing stimulation are both triggered using a footswitch. Both the reaching attempt detection and walk detection use accelerometers. As found in the literature, footswitches are the most reliable in detecting swing and stance phases for walking, and they require relatively simpler detection algorithms. Accelerometers were chosen for detection of reaching attempts by monitoring the tilt of the upper arm (details are given in Chapter 4). Gyroscopes could also be used for this purpose. However, as found in previous sections, gyroscopes suffer from drift and require the use of another sensor to compensate for the drift. In addition, the application does not require measuring an absolute angle value

therefore accelerometers were found to be more suited for this application. Accelerometers also were found to be the most suited for detection of walking since walking is accompanied with acceleration. Moreover, accelerometers are usually cheaper than gyroscopes which should keep the price of the proposed system low.

In order to overcome the problems found with wires, explained in previous sections, the system should be designed as a wireless network of sensors and stimulators. This leads to the next chapter which investigates wireless network technologies that can make FES systems wireless.

2.10 Summary

This chapter introduced the nervous system and some of the lesions that can affect motor functions. Injuries and diseases in the nervous system, causing motor dysfunction, can be classified in two main categories; lower motor neuron lesion and upper motor neuron lesion. Both conditions result in a different type of paralysis; the first causes flaccid paralysis in which the muscle is denervated and can only be stimulated by muscle stimulation. The second condition causes a spastic paralysis in which the muscle has intact lower motor neurons and can respond to nerve stimulation.

Electrical stimulation is an artificial technique to cause contraction of muscles. This can be used to assist paralysis by either muscle stimulation or motor nerve stimulation. Direct muscle stimulation requires high levels of current compared to nerve stimulation which could harm the skin. Therefore, functional electrical stimulation is usually reduced to nerve stimulation.

In FES systems, sensors are required in order to detect the periods requiring stimulation. There is a variety of sensors used in FES systems, and the most common are FSRs, kinematic sensors, and EMG. Depending on the application, some types perform better than others. Control methods of FES systems can be classified in two categories; open loop and closed loop.

Current FES systems are found to suffer from some impracticalities such as size of devices, wires causing reliability issues and cosmically unacceptable. Some of these issues can be addressed by new designs of FES systems, which are distributed and wirelessly connected. This is discussed in more details in the following chapter.

Chapter 3 - Wireless Networks for FES Applications

3.1 Introduction

FES systems consist of one or more stimulation units, one or more sensors, and a pair of electrodes for each stimulation channel. Electrode leads are used to connect electrodes to stimulation units. Depending on the FES application, sensors can be located distal from the stimulation unit (such as the footswitch in the drop foot FES system). These sensors are communally connected via wires to the stimulation unit(s). As explained in Chapter 2, wires can cause difficulties for users. In addition, wires are subject to breakage which affects the reliability. Therefore, replacing all wires connecting sensors and stimulation units might prevent failures caused by wires breakage, and increase the acceptance among patients.

Minimising the number of wires can be achieved by placing sensors directly in the stimulation unit(s) which eliminates the need for a wire from the sensor to the stimulator. However, as seen in Chapter 2, for some FES applications such as drop foot, the best performing sensors are placed distal from the stimulation unit. Therefore, for these applications, a wireless link from sensor(s) to the stimulator could solve the issues found with wires and optimise sensor performance. There are some commercial systems that already use a wireless link between a sensor (footswitch) and a stimulator such as the NESS L300 (Bioness, USA). This system was found effective as described by Hausdorff et al. [79]. Matjacic et al. [80] also designed a wireless hand switch, placed on crutches, to trigger FES assisted walking which helped patients in their daily activities such as entering and leaving a car, opening the door and using the toilet. Another application of wireless body-worn sensors is gait analysis, such as the system suggested by Benbasat et al. [81]. This system consisted of a wireless on-shoe sensor used to stream gait data to a computer for offline analysis. Their system was not designed to trigger stimulation, thus reliability and latency of the communication system do not affect the stimulation.

Wireless networks also allow designing a distributed multi-channel FES system in which stimulators can be designed to be small and placed where stimulation is needed.

This adds the advantage of sharing data from sensors to all elements of the network which eliminates the need of additional (replicated) sensors. For instance, heel events detected by a footswitch can be shared between the drop foot stimulation channel and the reciprocal arm swing stimulation channel. In addition, a wireless network can be expanded to include new elements (stimulation channels and/or sensors) if needed. This can minimise the costs of designing personalised systems. Wireless distributed FES systems have been proposed by some researchers. Toussaint et al. [82] suggested a closed loop wireless distributed therapeutic FES system. This system relies on a global controller which pilots a set of stimulation units. Jovičić [83] also proposed a distributed FES system, which consisted of stimulation nodes directly attached to electrodes to minimise electrodes leads. A central node was used to route all wireless traffic and which can be attached to a computer to give real time monitoring of stimulation and on-the-fly changes of stimulation parameters. The central node adds an additional element to the system and all communications rely on it. This could be a disadvantage as in the event of failure of this central unit, the whole system fails and stops working. Moreover, users will be obliged to carry this unit all the time although it does not have functional role in the FES system.

Each element of the wireless FES system, stimulators and sensors, needs to integrate a wireless module, controller/processor, and a separate energy source (battery). This therefore brings new factors that could affect the performance of the system which are; wireless interference, increased latency, and increased power consumption. Therefore, any chosen wireless technology for this application needs to meet a specification that ensures performance, matching or approaching that of a wired system.

This chapter explains the requirements for any chosen wireless technology to be used for FES systems. It explains the importance of the specification of the wireless system, and compares the available wireless technologies.

3.2 Wireless requirements

Functional electrical stimulation systems are designed to improve the quality of life of patients and improve their mobility safely and consistently. Therefore, every FES system designed must be reliable in all conditions that the user may face in their daily activities. Moreover, it should operate consistently with minimum delays and latencies. This ensures the safety of the user since failure to generate stimulation on time or

completely missing one stimulation burst might cause a risk for the user. For instance, one missed stimulation burst could cause the user to trip if they rely on a drop foot stimulator to clear their foot from the ground while walking.

Wireless communication systems are subject to interference from other systems which are sharing the same frequency spectrum. This can result in loss of communication or can cause delays depending on the technology. Wireless networks use communication protocols which enable point to point communication and also can integrate a collision avoidance to ensure reliable communication. However, these network protocols often cause delays in the transmission of messages.

As the system requires communication between elements worn on the body, the chosen technology should be a short range wireless network. These networks cover only few meters in order to minimise interference with both: other users of the same system and other wireless devices. In order to reduce the costs and to make the system accessible to many patients, the wireless technology should be simple and cost effective. High bit rate is not a priority in this application since only command messages are transmitted and not continuous streaming of data. However, the higher the bit rate, the shorter is the time to transmit packets and therefore the latency.

Therefore, the wireless communication technology chosen for this application has to meet the following requirements: high reliability, low latency, and low power consumption.

3.2.1 High reliability

Reliability is important in this system since patients will rely on it to perform functional movements, and any failure that could interrupt or stop the required function being provided could be a risk. On the other hand, the importance of reliability is relative to the application. For instance, patients relying on a drop foot system to walk can trip if they do not receive stimulation on time, which is a high risk. However, for a hand opening stimulator, any failure is not a significant risk to the user. This is due to the fact that failure of stimulation will only result in not opening the hand and requires another attempt to trigger. Nevertheless, it might lead to frustration of the user and reduce its acceptability.

The wireless system has to approach the reliability of the wired system. This will increase the confidence of users in using such devices. Reliability of the system depends

on the wireless technology chosen which has to be robust against interference. Wireless interference is likely to occur in this application due to the fact that users will be using the device at home and outside, thereby being subjected to different sources of interference.

The current wired system is considered 100% reliable as long as the wires are not detached or damaged. However, wired connections are likely to fail as explained in Chapter 2. This affects the overall reliability of the wired system which in practice is less than 100%. It is practically difficult to quantify this unreliability since failures generally happen when patients are away from clinic, and hence patients usually do not record these events. Therefore, a wireless system that can ensure reliability approaching 100% will match the wired system.

3.2.2 Low latency

Latency is usually higher in wireless networks than wired ones. This is due to the more complicated network protocols used to ensuring reliability of communication. Therefore, when choosing a wireless technology, it is necessary to consider the protocol used which should not lead to high latencies, and as a result, does not affect the effectiveness of the FES system.

The literature does not specify what an acceptable latency for FES application is. Therefore, this research project (Chapter 4) defines experimentally a maximum value of acceptable latency to which the system can be verified against, and in addition, investigates the effect of delayed stimulation to the efficacy and safety of gait.

3.2.3 Low power consumption

One disadvantage of using a wireless technology is the need for a separate power source for each node of the network. This raises the issue of power consumption since the wireless system should be usable for at least one day with the same batteries. Therefore, choosing the wireless technology to be employed for FES applications should be characterised by low power consumption in order to maximise battery life.

For this project, an off-the-shelf wireless communication system is preferable since the aim of this project is not to design a wireless communication system, but to use one in a FES system. Moreover, designing a wireless network is a lengthy process (wireless standards usually take years to be established) and requires a team of engineers to

design a robust wireless network. As a result, an existing technology available on the market was adapted to this application.

3.3 Wireless technologies

Nowadays, many standards of wireless technologies are available, ranging from long distance networks to short range networks. However, not all of them are commercially available.

Off-the-shelf short range wireless technologies perform at a variety of bit rates, power consumptions and cost. As mentioned in [84], there are mainly three short range wireless communication standards, known as Wireless Personal Area Networks (WPAN), that are commercially available and are therefore suitable to be used for body worn applications. The following table gives a comparison of these standards.

Features	IEEE 802.11 (Wi-Fi)	IEEE 802.15.1 (Bluetooth)	IEEE 802.15.4 (ZigBee)
Average battery life	Hours	Days	Years
Average cost per module (large volumes)	$9	$6	$3
Complexity of protocol and hardware	Very complex	Complex	Simple
Radio spectrum	2.4GHz	2.4GHz	868MHz, 915MHz and 2.4GHz
Max data rate	1 to 54Mbps	1 to 3Mbps	20 to 250Kbps
Network size	32 nodes	7 nodes	64 000 nodes
Range	30 to 100m	2 to 10m	10 to 100m
Applications	High-bandwidth applications	Low-bandwidth cable replacement	Low-bandwidth sensors and automation

Table 3.1: Comparison of the main available short-range wireless technologies [84],[85]

As shown in table 3.1, ZigBee standard has a clear advantage over Wi-Fi and Bluetooth in terms of battery life, cost, simplicity, and network size. On the other hand, Wi-Fi has the highest bit rate while ZigBee has the lowest bit rate of 250Kbps (2.4GHz band). At this bit rate, a frame of 30 characters (240 bits) for example will be 960µs long plus the headers. So even at this low bit rate, short messages will take less than 1ms which represents less than 5% of the period between two stimulation pulses (maximum

stimulation frequency is 50Hz as recommended by Backer et al. [11]). Therefore, this transmission time is acceptable in FES applications.

The table shows also that the three technologies share the 2.4GHz band which means that it is very likely that the three could interfere with each other. Shin et al. [86] investigated the coexistence of the three technologies in indoor conditions and concluded that they can coexist with low data errors if distance between sources is greater than 12m.

The other characteristic of this frequency band (2.4GHz) is its reduced capability to penetrate the human body. This might affect the propagation of electromagnetic waves at this frequency around the human body. Gallo, et al. [87], and Hoa, et al. [84] investigated using a body-centric wireless network in this frequency band. They suggested that although these waves do not penetrate the body easily, waves curved around the body making it possible to propagate around the whole body. In addition, Valdastri et al. [88] have shown that it is feasible to use a ZigBee communication system for implants which can communicate from inside the body to an external base station. These waves can also reflect from walls and many other objects making coverage around the body in indoor conditions more likely to be sufficient to ensure reliable communication. Therefore, the environment that is likely to cause the poorest coverage of the whole body with this frequency band would be in open spaces.

There are other short range wireless technologies that are still in the development and standardisation process such as the IEEE 802.15.6 known as Wireless Body Area Network (WBAN) which was expected to be accomplished by 2010 as mentioned by Hoa et al [84]. A draft of this standard has been approved in July 2011 [89], but it has not been released at the time of writing. Ultra Wide Band (UWB) is another project of a short range network standard developed under the IEEE 802.15.3a for a high bit rate WPAN. Work on this standard was withdrawn in 2006 [90]. This standard was replaced by the IEEE 802.15.3c known as Millimetre-Wave WPAN which was released in 2009 [91]. This technology enables a high speed communication over a short range. The frequencies used are in the 60GHz band. Commercial modules of this standard are not yet available.

Yuce et al. [92] propose a WBAN using the MICS (Medical Implant Communication Service) frequency band operating from 401 to 406MHz, and the WMTS (Wireless

Medical Telemetry Service) which operates in three bands 608-614 MHz, 1395-1400 MHz and 1427-1432 MHz (USA only). Wang et al. designed a 1V wireless transceiver that can be used for telemetry at a data rate of 50Kbps [93]. These systems are suggested as a standard for WBAN, however the process of standardisation could be lengthy and sometimes come to a hold as a result of disagreement between participants (for example, the IEEE 802.15.3a group).

There are some other proprietary standards based on the IEEE 802.15.4 standard such as MiWi [94] which shares the physical layer and Medium Access Control (MAC) layer with ZigBee, and differs in the network protocol layer. The disadvantage of such systems is that the stack is closed and can be developed only by the publishers. So the continuous improvement and the survival of the standard depends on the will of the publishers. Therefore, this work will not consider proprietary standards and will only use well established and recognised technologies.

The wireless technologies, from the ones mentioned above, that are relevant to this application are Bluetooth and ZigBee. Since both are the only ones to be short range and portable technologies. ZigBee has the advantage of lower power consumption and complexity. In addition, ZigBee is more reliable according to Baker [95]. Baker compared the two technologies for industrial applications and concluded that ZigBee is better suited for remote sensing. Considering the similarities of the present application to the industrial applications mentioned in [95], including remote sensing and wireless control, ZigBee is chosen as the wireless technology for the implementation of this project.

Recently, Bluetooth Low Energy (BLE) has appeared in the market, such as the BLE modules from Bluegiga Technologies Inc, Finland, which were released at the beginning of 2011 [96]. This technology is promising since it is designed to be ultra low power and low latency. This technology was not available when the choice of the wireless technology for the present application was made. Moreover, this technology can work only in star topology while ZigBee can work in both star and mesh topologies (Network topologies are explained in the following sections). Therefore, the wireless technology best suited for this application is still ZigBee for the reasons mentioned above.

3.4 ZigBee

ZigBee is a standard for low power, low bit rate and short range wireless network. The standard is a set of network protocol layers that sits on top of the layers specified in the IEEE 802.15.4 standard. In turn, IEEE 802.15.4 is a low rate WPAN standard specified by IEEE which defines the physical layer and the Medium Access Control (MAC) layer (see [97] for more details).

As specified in the IEEE 802.15.4 standard, the physical layer can work on three unlicensed frequency bands 868 MHz, 915 MHz and 2.4GHz. The maximum bit rate is 250Kbps achievable only in the 2.4GHz band. In addition, the ZigBee protocol is designed to reduce the active time of the device (in low power mode) to a minimum which results in considerable reduction of power consumption.

ZigBee is the outcome of collaboration between hundreds of companies under the ZigBee alliance which was formed in 2002. For more details on ZigBee refer to [98], [85] and [99].

3.4.1 ZigBee architecture

The architecture of ZigBee consists of four main protocol layers represented in Figure 3.1.

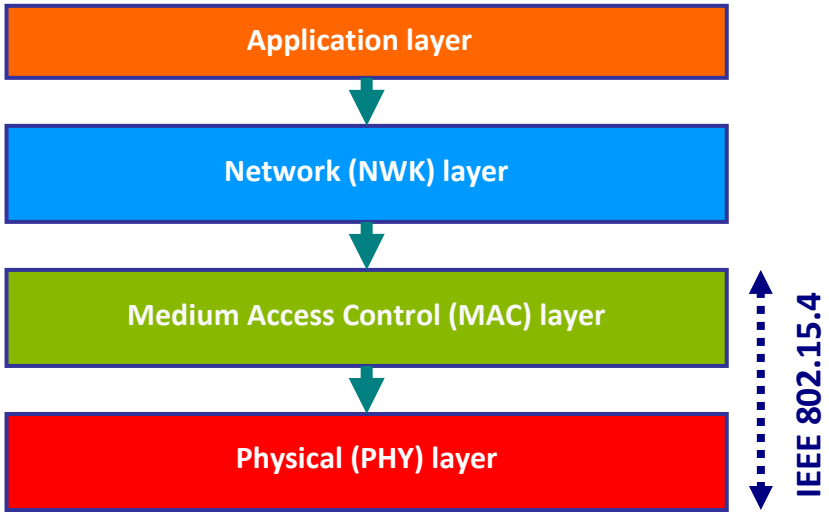


Figure 3.1: Architecture of ZigBee

3.4.1.1 Physical layer

The physical (PHY) layer is the lowest protocol layer in ZigBee which directly controls and communicates with the transceiver. Its functions include selection of the radio

channel, Energy Detection (ED), Link Quality Indication (LQI) and Clear Channel Assessment (CCA).

ED is used in the channel selection process which consists of measuring the received energy in one of the channels specified in the IEEE 802.15.4. LQI is used to indicate the quality of the link which is based on the Signal to Noise Ratio (SNR) or the Received Signal Strength (RSS). CCA is essential for a reliable communication in ZigBee since it can be set to measure the energy in the channel and/or report a busy channel (involving identification of the signal) to consider whether the channel is available or not before transmission.

3.4.1.2 Medium access control

The Medium Access Control (MAC) layer provides an interface between PHY layer and the network layer. It generates beacons and acknowledgement frames of delivery. Beacons are used in the MAC to synchronise ZigBee devices together, and the acknowledgement frames to notify the transmitting device of the successful delivery. MAC manages channel access and association/disassociation of devices to a network. The MAC layer also runs the Carrier Sense Medium Access with Collusion Avoidance (CSMA-CA) algorithm. This allows multiple devices to share the same radio channel. CSMA-CA requests a CCA to ensure the radio channel is clear before transmission. If the channel is not clear, the transmission attempt is backed-off for a random period of time and repeated until the channel is cleared or it reaches the maximum number of repeats defined by the user.

3.4.1.3 Network layer

The network (NWK) layer manages the network information and routing. The network information includes establishing and maintaining a network, selecting a network topology and assigning network addresses to devices. Routing consists of defining a path through which messages are relayed from a transmitting device to a receiving device (could involve other devices to forward the message, depending on the network topology).

3.4.1.4 Application layer

The application layer is the top protocol layer in ZigBee and hosts application objects to customise the function of the network. The application intended for a ZigBee device can

be based on application profiles which are a set of agreements on message formats and processing actions. The use of application profiles allows interoperability between devices manufactured by different vendors.

3.4.2 Frequencies of operation and data rates of ZigBee

IEEE 802.15.4 specifies three frequency bands as shown in the following table:

Frequency (MHz)	Number of channels	Bit rate (Kbps)
868-868.6	1	20
902-928	10	40
2400-2483.5	16	250

Table 3.2: ZigBee operating frequencies and bit rates [85]

The 868MHz band can be used in Europe where it is allowed to use this band for some short range wireless networks.

The 915MHz band (902-928 MHz) is an Industrial, Scientific and Medical (ISM) band and available mainly in North America.

The 2.4GHz (2.4-2.483GHz) is an ISM band available worldwide.

The specification of the 868 and 915 are simpler to implement however have the disadvantage of lower bit rate. The advantage of the 2.4GHz band is that it is available world wide [85]. Moreover, the 2.4GHz has more channels available (16 channels) as shown in table 2. This can be used to avoid interference by choosing a quiet channel. For these reasons the application of this research was based on the 2.4GHz option of the IEEE 802.15.4 standard.

Selection of ZigBee channels is done at the time of establishment of a new network and does not change during operation unless the network is re-established. ZigBee uses Direct-Sequence Spreading Spectrum (DSSS) to improve the coexistence with other devices and to improve the performance in multipath environments.

In the 2.4GHz band, the 16 ZigBee channels are 5MHz wide, as illustrated in Figure 3.2

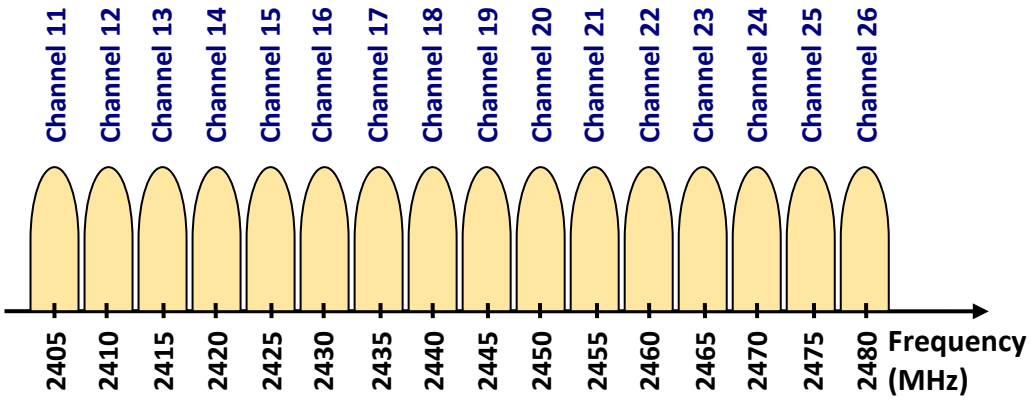


Figure 3.2: ZigBee channels (2.4GHz band)

3.4.3 Device types and roles in ZigBee

IEEE 802.15.4 specifies two types of devices; Full Function Device (FFD) and Reduced Function Device (RFD). The difference between the two is that the FFD is implemented with the full network duties specified by the IEEE 802.15.4 standard, such as routing messages to multiple nodes. On the other hand, RFD is capable of only partial duties which makes these devices able to communicate with only one FFD device and therefore, can not forward messages. The advantage of limiting network duties in a node is to reduce power consumption by sending the node to low power mode (sleep). When a RFD is put to sleep, the transceiver can be switched off and enabled only for a short time periodically or when a message is ready to be transmitted. Receiving messages can be done only when the transceiver is enabled. As a result, receiving messages in this mode can be delayed depending on how long is the period set to enable the transceiver. So to minimise latency, any device expected to receive messages with the lowest delay possible should be kept continuously in full power mode.

The network coordinator and any routing node must be an FFD, the rest of the nodes can be either FFD or RFD. Sensor nodes are preferably set as RFD since they generally only transmit and are not affected by delays in receiving messages. This helps in designing sensor nodes with a small battery since the power consumption is low in RFDs.

ZigBee networks are formed by setting one of the FFDs as the network coordinator known as Personal Area Network (PAN) coordinator. This FFD creates and joins the network. The remaining nodes (FFD or RFD) are allocated network addresses by the PAN coordinator which must be enabled at the time of joining.

3.4.4 Network topologies of ZigBee

ZigBee allows formation of two network topologies; the first is the star topology which consists of a PAN coordinator and multiple nodes that can only communicate directly with the coordinator. Any communication between nodes is routed through the PAN coordinator. The second topology is mesh topology which allows direct communication between multiple nodes without necessary going through the coordinator. These nodes are called routers, as they can route communication without involvement of the PAN coordinator. In addition, these nodes and all the nodes communicating directly to them do not require the presence of the PAN coordinator once the network is set. Both topologies are represented in Figure 3.3.

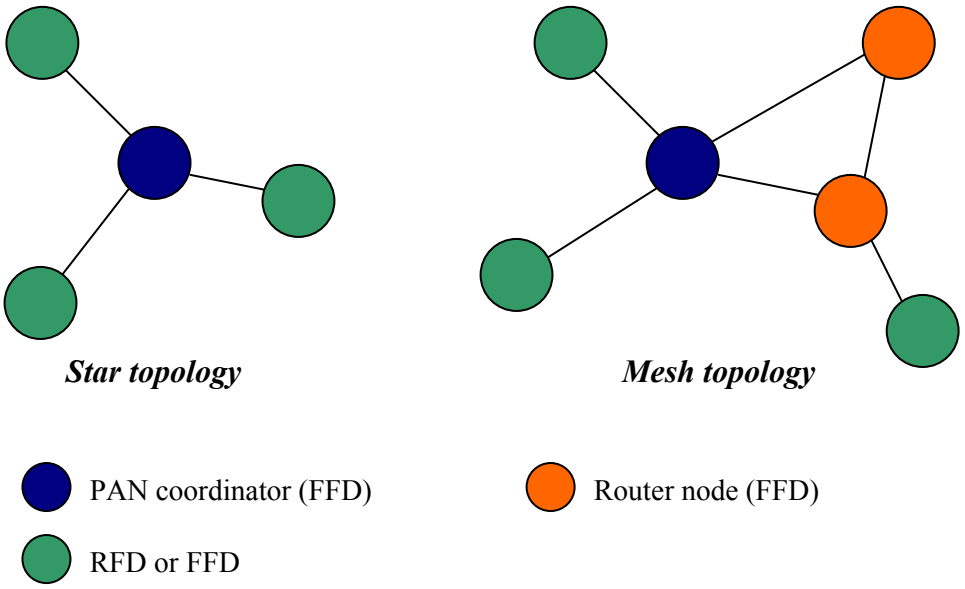


Figure 3.3: Network topologies of ZigBee

The advantage of the star topology is that, except for the coordinator, all devices can be made RFDs and switched to low power mode (also known as sleep mode). In the mesh topology, on the other hand, not all devices can be made RFDs since devices which are communicating directly with more than one device must be FFD. Therefore, these devices can not be put in low power mode. To illustrate this, the wireless ZigBee module "ZigBit A2" (Meshnetics, Germany) has a power consumption of 18mA in the active mode and 6µA in sleep mode. If one of the devices is in sleep mode (e.g.: sleep for 1s and active for 200ms), the power consumption will drop to less than 17% of what the device in active mode consumes ([6µA × 1s + 18mA × 200ms] ÷ [1s + 200ms] = 3mA).

A mesh topology is more reliable than a star topology when one link is lost between two FFDs. Messages can be re-routed through other devices in the network to bypass the lost link. However, this will result in an increased latency for every node the message hopes through. Mesh topology has also the advantage of direct communication between nodes (FFDs only) without routing through the coordinator. This is an advantage in a network where some nodes need communication with only a few others. For instance, the network can be designed as a connection of multiple star topologies where communication is needed only within the sub-network (star topology). This decreases the latency of transmission between two nodes that are not the network coordinator.

Choosing which of the topologies to adopt for the present application depends on the maximum latency and power consumption acceptable and how messages need to be routed. The proposed application consists of three stimulator nodes (they include sensors as well) and a sensor node (in-shoe). The system is aimed to have the drop foot as the main application so the drop foot stimulator node was defined as the PAN coordinator. Stimulation nodes need to react to any event as quickly as possible and can communicate together. Therefore, these nodes needed to be FFDs and active all the time. The sensor node, on the other hand, was set as a RFD since it is expected to run on a small battery to fit in the shoe and is not expected to receive messages as fast as possible. However, this meant that the sensor in the shoe can communicate directly with only one of the stimulator nodes. From the three stimulation channels, drop foot is the most critical in terms of stimulation timing. Therefore, the sensor in the shoe was set to communicate directly to the drop foot stimulator node which forwards messages to the other two nodes if needed. Therefore, the chosen topology was a mesh network consisting off three FFDs and one RFD.

3.5 Summary

Wireless networks are suggested to bring advantages if used in multi-channel FES systems. A wireless FES system might be more convenient to the user than a wired system, and could prevent reliability issues found in the wired system due to wire breakage. However, any chosen wireless technology must meet three requirements to ensure effective function of the FES system. The requirements include; high reliability in transmitting and receiving messages for safety implications, low latencies, and low power consumption to allow powering nodes with small batteries.

ZigBee appears to be the best suited technology for wireless FES applications, from the commercially available systems. ZigBee has low power consumption and low complexity compared to Wi-Fi and Bluetooth. In addition, ZigBee allows mesh network topology which was found the most suited for the present application.

Therefore, in this project, ZigBee modules were used as the wireless interface. However, experiments still needed to be done to verify the requirements of the system. As a result, prototypes were designed and built to perform the tests which are explained in the following chapter.

Chapter 4 - Experimental Methods

4.1 Introduction

The main objectives of this project are to investigate the feasibility of a wireless distributed FES system and design a three-channel system with automated control. This work can therefore be split in two stages. The first stage is to investigate a wireless FES system and evaluate the performance of the system. As explained in Chapter 3, the chosen wireless technology used in this project is ZigBee. Therefore, a prototype wireless single channel stimulator is to be designed, built and tested. This prototype consists of two wireless nodes used in experiments to estimate the reliability, latency and battery life of the system. These three requirements are explained in Chapter 3. The maximum acceptable latency could not be found in the literature, and therefore this was estimated experimentally as described in this chapter.

The second stage, after achieving acceptable performance of the wireless system, was to design and build the wireless distributed three-channel stimulator. The function of the second prototype, as explained in Chapter 2, is to stimulate drop foot and reciprocal arm swing in walking mode, and reaching and grasping in standing/sitting (stationary) mode. The concept of such a wireless FES system was explained in a poster presented at a conference [100] (appendix L).

Multiple experiments have been designed and performed, for each stage, in order to answer the two research questions. This chapter describes the experiments performed and the prototypes used in the experiments.

4.2 Defining latency specification

Communication systems introduce latency caused by the time it takes to prepare messages for transmission and the transmission. The value of communication latency depends on the communication protocol. Latency could affect the efficiency of FES systems. This project therefore investigates the maximum latency acceptable for drop foot stimulation which might be affected by delays more than other FES applications, as

explained in Chapter 3. It also investigates the effect that delayed stimulation has on drop foot users.

4.2.1 Dorsiflexion timing experiment

The first method used to define the maximum acceptable latency for drop foot stimulation was by looking at the dorsiflexion timings in relation to heel events in unimpaired subjects. Therefore, an experiment was designed to measure time between heel rise and start of dorsiflexion of the foot, and the time between heel strike and the end of dorsiflexion. Dorsiflexion of the foot was identified by measuring the EMG activity of the group of muscles responsible for it (Tibialis Anterior). This experiment was performed on healthy volunteers who have clear dorsiflexion of the foot during swing phase.

The equipment used for this experiment was an EMG amplifier to amplify the surface EMG signal from the tibialis anterior using surface electrodes. Heel events were detected using a microcontroller (PIC18LF PIC18LF14K22, Microchip) running the same detection algorithm used in the ODFS Pace stimulator (Odstock Medical Ltd, UK). The microcontroller was programmed to generate a digital output representing heel events (rising edge for heel strike and falling edge for heel rise). This signal was used when processing data as a reference for the EMG signal. Signals were acquired by an analogue to digital converter with synchronised inputs at a sampling frequency of 2.5 kHz. This sampling frequency was chosen to satisfy Nyquist rate since the bandwidth of the EMG amplifier is 20-450 Hz. The recorded signals were saved in comma-separated value file format.

The EMG amplifier used for this experiment was designed and built by a Clinical Scientist trainee (R. Batty, Department of Clinical Science and Engineering, Salisbury District Hospital, UK).

Four healthy volunteers were recruited for this experiment. They were asked to walk at three speeds (their normal pace, faster than normal and slower than normal) for a distance of 10m. The walks were repeated four times at each speed.

The data was processed in Microsoft Excel, in which EMG data was grouped in two periods; the first was from heel rise to heel strike (simplified here to swing phase) and the second was from heel strike to heel rise (simplified here to stance phase). For each walking speed, data of each gait phase was normalised and averaged to reduce noise,

resulting in one averaged data for swing phase and one for stance phase per walking speed. The resulting data was used to produce two graphs per volunteer per speed (i.e. six graphs per volunteer) which are used to estimate timing of dorsiflexion for each volunteer at three speeds and investigate if there is any difference between volunteers and at different speeds.

All equipment used for this experiment was isolated from the mains power to meet safety requirements. The EMG amplifier was designed to meet the IEC 60601-1 requirements for medical equipment. In addition, the footswitch hardware had no direct contact to the volunteer since the microcontroller circuit is housed inside a plastic box, with isolated cables and FSR (Footswitch, Odstock Medical Ltd).

4.2.2 Effect of delayed stimulation on drop foot users

The purpose of this study is to determine if there is any reduced performance caused by delayed drop foot stimulation as a result of using the wireless footswitch. The volunteers recruited for this experiment were stroke patients who are already using drop foot stimulation. This experiment did not require NHS ethical approval since it did not involve NHS patients or staff as recommended by South West Research Design Service (SW RDS) (See Appendix A). Ethical approval was granted from Bournemouth University (Appendix B).

In this study, stimulation bursts were delayed by values from 0 to 250ms using a standard ODFS Pace stimulator (CE marked). The experiment took place in a gait analysis laboratory (Salisbury District Hospital, Salisbury, UK). The laboratory was used to capture motion of the participant's lower limbs using the Vicon MX (Vicon motion systems, UK). The captured motion was used to estimate the angle of dorsiflexion while the participant is walking. The feedback from the patient was recorded as well as the clinician's. In addition, a video was recorded of each session which was used to analyse the data.

The feedback from both, the clinician and patients, consisted of a scoring system and comments on each introduced delay. The scoring system was based on giving a number between 1 and 10 for each trial; 1 for unsatisfied and 10 for satisfied about stimulation. Patient DS03 preferred to use a different scoring system which consisted of giving a score of five to the first trial (no delay) which was used as a reference. The patient then

gave higher scoring (more than 5) if stimulation was felt better than the reference, and lower scoring (less than 5) if stimulation was felt less satisfying.

A clinician from the National Clinical FES Centre (Odstock Medical Ltd) identified and contacted drop foot users and who were selected to take part of a trial on the wireless footswitch (section 4.3.3.2). The clinician set up the drop foot stimulator to suit the patients' needs. The clinician was also asked to record comments on the effectiveness of stimulation for each trial (each delay introduced).

Participants were asked to undertake two walks of 10m for each introduced delay. The delay values were: 0ms, 25ms, 50ms, 75ms, 100ms, 150ms, 200ms, 250ms, and repeated 0ms. Therefore overall, 18 trials were performed for each subject.

4.3 Wireless testing

As explained in Chapter 3, a suitable wireless system can be quantified by three main characteristics; reliability, latency, and power consumption. The first prototype was designed and built to estimate these three characteristics. This section starts with defining a maximum latency requirement for the proposed system.

4.3.1 Wireless prototype (first prototype)

The prototype was a wireless single channel drop foot stimulator consisting of a wireless footswitch (footswitch node) and a wireless stimulator (stimulator node). This application was chosen for the first prototype because FES walking systems rely on high reliability and low latency for the safety of the user. Any missed or delayed stimulation while walking could cause the patient to trip and fall. Other applications, such as upper limb stimulation for reaching and grasping, do not cause as high a risk of failure as drop foot stimulation. Furthermore, drop foot stimulation is the most used clinically, so the outcome of this research would be beneficial for a large number of FES users if it is proven that the system is as effective as the current (wired) system. In this case, it could be used to develop a wireless drop foot stimulator product.

4.3.1.1 Wireless module

Choosing the ZigBee module was based on comparing all the available modules in the market in terms of power consumption, latency, size, and price. Size was important since the wireless module was planned to be integrated in the ODFS Pace case. Moreover, the smaller the module is the smaller the footswitch node hardware. The first

choice was the ZigBit module (Mechnetics, Germany) which had the lowest power consumption and smallest size of all (Appendix C). However, the command language used to set and control these modules (AT command set) did not offer a wide rage of commands sufficient to implement the functions needed for this application. The alternative to this was to modify the highly complicated stack (firmware of the wireless module). Moreover, the measured latency on these modules was found to exceed 50ms in sleep mode which was relatively high compared to other commercial modules.

The second choice was ETRX3 (Telegesis, UK) which is the second smallest of all and has low power consumption (Appendix D). Initial latency tests showed better performances than ZigBit; measured 9ms in full power mode and 15ms in sleep mode. This module also offered much larger flexibility in terms of functions and control of the ZigBee protocol. As a result, ETRX3 has been chosen to be the wireless module to be used as communication interface for the proposed prototype. The average cost of the ETRX3 module is £12 per unit (orders < 100 units).

4.3.1.2 Footswitch node

The designed wireless footswitch (Figure 4.1) includes a microcontroller (PIC18LF14K22, Microchip) to perform the footswitch detection algorithm. The detection algorithm is the same algorithm used in the ODFS Pace stimulator since it is proven to be reliable. The FSR (Odstock Medical Limited, UK) was designed to be used in a voltage divider circuit to vary the voltage across it depending on the force (pressure) applied. This voltage is fed back to the microcontroller. The wireless footswitch also includes an accelerometer (ADXL234, Analog devices). This accelerometer was not used in this first stage of the research and was included to be used in the final prototype which will be explained later in this chapter.

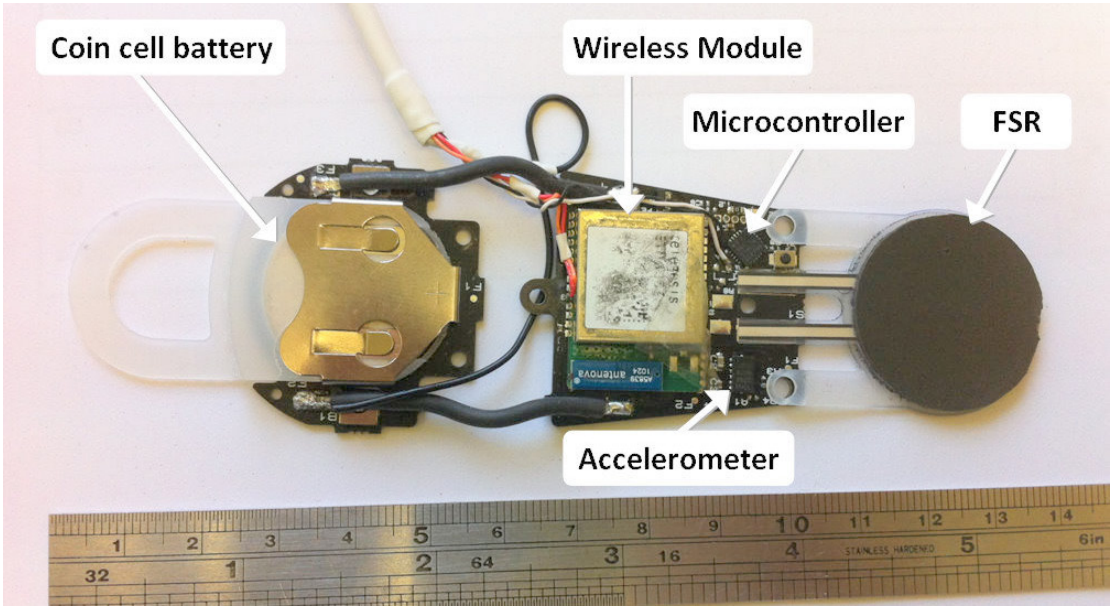


Figure 4.1: Wireless footswitch hardware

The microcontroller also controls the wireless module ETRX3 (Telegesis, UK), included in this node, in order to trigger transmission of heel events when they are detected. For this application, the acknowledgement (ZigBee functionality) is disabled which was slowing the rate of transmissions. Acknowledgement is a ZigBee protocol functionality that enables the transmitter to know whether the transmitted message is received. This works by sending an acknowledgment message from the node receiving a message to the node that transmitted the message. So if the transmitter does not receive an acknowledgement message within a period defined in ZigBee protocol, a retransmission of the message is performed and this sequence can be repeated until the message is received or it reaches the maximum number of repeats (more details are found in [85]). As a result, messages are more likely to be received and the reliability of transmissions is increased. However, this also results in increased transmission time and might cause messages to be buffered if the transmission rate is slower than transmission request rate. For this reason, the acknowledgement was disabled for this project to minimise transmission time and therefore latency. The consequence of this is permanent loss of any message not received successfully the first time.

As a precautionary measure, the code was initially designed to send the detected event twice; first transmission when the event occurs and the second one of the same event following after 50ms. This value of separation time was chosen because it was found experimentally that transmissions separated by less than 50ms clog the transmission

buffer of the ZigBee module. This experiment involved setting the wireless module to transmit a message at every rising edge of one of its digital inputs. This digital signal was generated using a frequency generator (GFG-8020H, Gw Instek). The frequency of the generator was increased from 1Hz until irregularities of transmission were recorded, which started to appear at 20Hz.

The redundant transmission was first thought to double the chance of receiving the message successfully. However, after some tests, this was found to cause the receiver to count a step twice, if the second transmission is buffered and received after the first transmission of the following event. For instance, in one step (heel rise, heel strike), messages could be received as the following sequence: "heel rise (1^{st} transmission), heel strike (1^{st} transmission), heel rise (2^{nd} transmission), heel strike (2^{nd} transmission)" instead of the expected sequence: "heel rise (1^{st} transmission), heel rise (2^{nd} transmission), heel strike (1^{st} transmission), heel strike (2^{nd} transmission)". Moreover, this method requires more processing at the receiver node to differentiate between a retransmission of a received event and a new event. In addition, it increases power consumption in both nodes because of the double amount of data to transmit and to process. For these reasons, this idea was withdrawn and only one transmission was made per event.

In order to reduce power consumption, the wireless module was set to work in sleep mode (low power mode, sending the transceiver and the microcontroller of the module to sleep). In the occurrence of a heel event the wireless module is interrupted to send the appropriate message and then sent back to sleep.

For experimental purposes, one digital output signal was generated and assigned to one output line. This signal represents the detected events; the signal was set high when heel strike is detected and set low when heel rise is detected.

The electronic circuit of the wireless footswitch node was designed by S. Finn (Clinical Engineer, OML) with some input from the author. The mechanical design of this node was produced by D. Nolan (Clinical Engineer, OML). The firmware of the wireless footswitch was designed and written by the author with support from S. Finn.

4.3.1.3 Stimulator node

An expansion board was designed to be connected to the commercial stimulator ODFS Pace which already was designed to be triggered externally. The connection was

achieved through a 12 pin connector including serial communication lines (SPI protocol) and five Input/Output (I/O) lines. The expansion board consists of a microcontroller (PIC18F46J50, Microchip), a wireless module (ETRX3, Telegesis), and a three axis accelerometer (ADXL234, Analog Devices) as shown in Figure 4.2. The microcontroller controls the wireless module by generating the messages to be transmitted based on commands from the Pace, and processes the received data. When an event is received from a sensor requiring starting/stopping stimulation, the microcontroller on the expansion board translates that in one of the I/O lines to the ODFS Pace by setting the logic level high or low. For this first prototype, falling edge represents heel rise, and rising edge represents heel strike. The accelerometer was also included in this node for the final prototype.

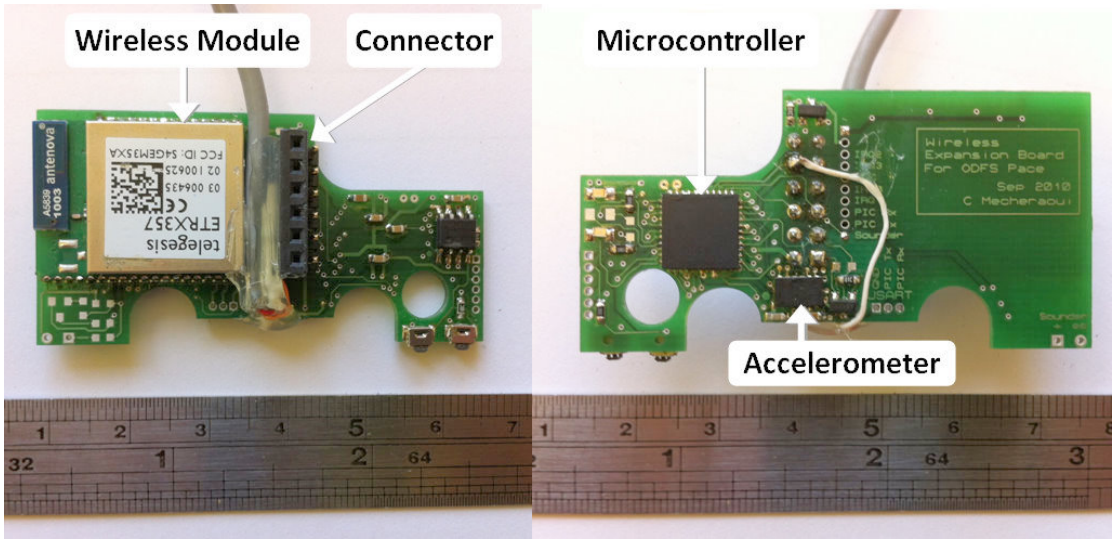


Figure 4.2: Expansion board used in the ODFS Pace as wireless stimulator node

For experimental purposes, the expansion board was designed to give one digital output which represents the stimulation triggering signal. This signal is set low when a heel rise message is received and set high when a heel strike is received. This signal is then recorded and compared with the one from the wireless footswitch to measure reliability and latency.

The electronic circuit of this node was designed by the author based on an initial design by R. Batty (Clinical Engineer, OML). The modifications were made to enable the functions proposed in this research and additional debugging lines. Two main versions of the firmware for this node were designed and written by the author with support from R. Batty. The first version was designed for the single channel system, and the second

version included additional functions to enable the system to work as a distributed multi-channel system.

4.3.1.4 Data logger

A data logger was needed to collect and record the two digital outputs (one from the footswitch node and one from the stimulator node) used to measure reliability and latency. The logger needed to be portable since some of the experiments were performed outdoors. Some experiments were performed for more than an hour and the sampling rate needed to be less than 10ms since the latency could be as low as 9ms. As a result, the logger needed to cope with large amount of samples. All the off-the-shelf loggers available to the author, from Bournemouth University and OML, did not meet the needed requirements, and the commercially available ones that met the requirements were costly.

As a result, a customised data logger was designed and built by the author for this specific application. The logger was designed to be portable and connects to a computer via serial port. The sampling rate of this device was set to 0.5ms and data can be collected uninterrupted for as long as the device is powered. This sampling rate gives a resolution of 500µs which represents 5.55% of the minimum measured latency of the wireless module. It also represents 2.5% of the shortest stimulation period (equivalent to 50Hz).

The designed data logger, presented in Figure 4.3, consists of a microcontroller (PIC18LF14K22, Microchip, USA) which is set to be interrupted by any change of one of the two digital signals. This triggers recording of the event and the time of the event. The microcontroller uses an internal timer interrupt to increment a variable every 500µs that was calibrated using a calibrated scope (Tektronix TDS2014).

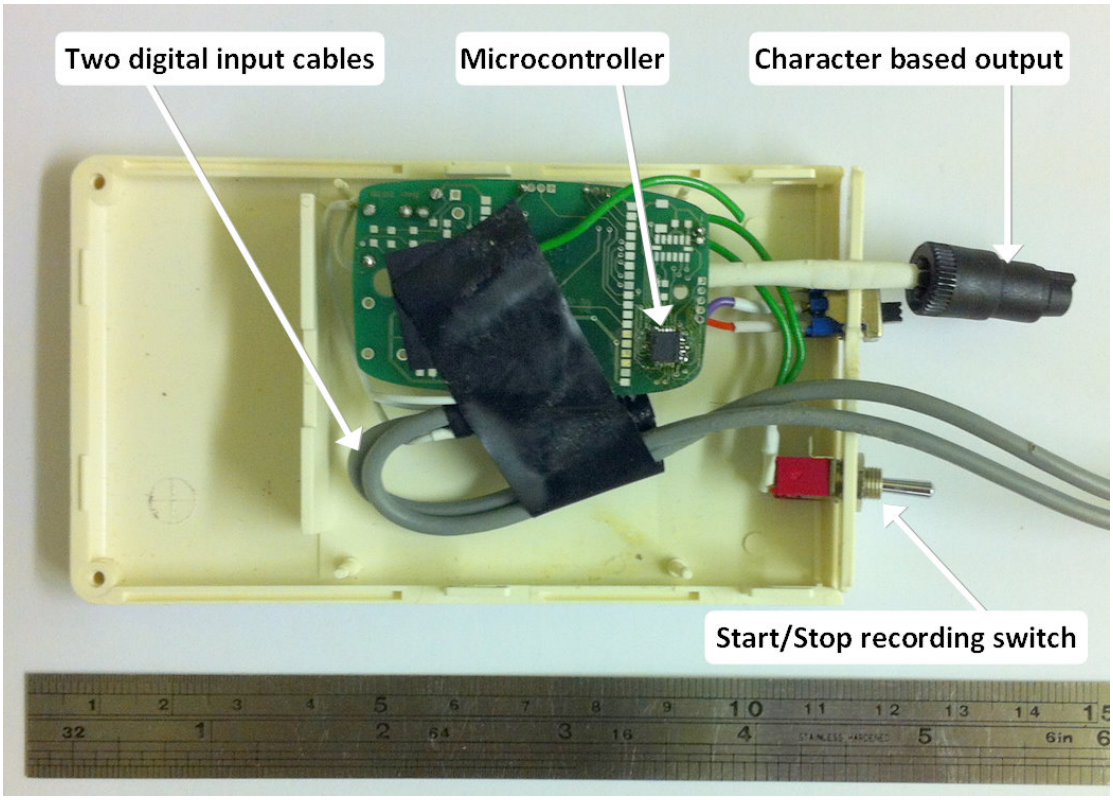


Figure 4.3: Data logger hardware

The data logger follows the flowchart given in Figure 4.4. The timer is reset to zero on every rising edge of the footswitch signal. So all events are timed to the previous heel strike on the footswitch (rising edge), including the new heel strike on the footswitch before resetting the timer.

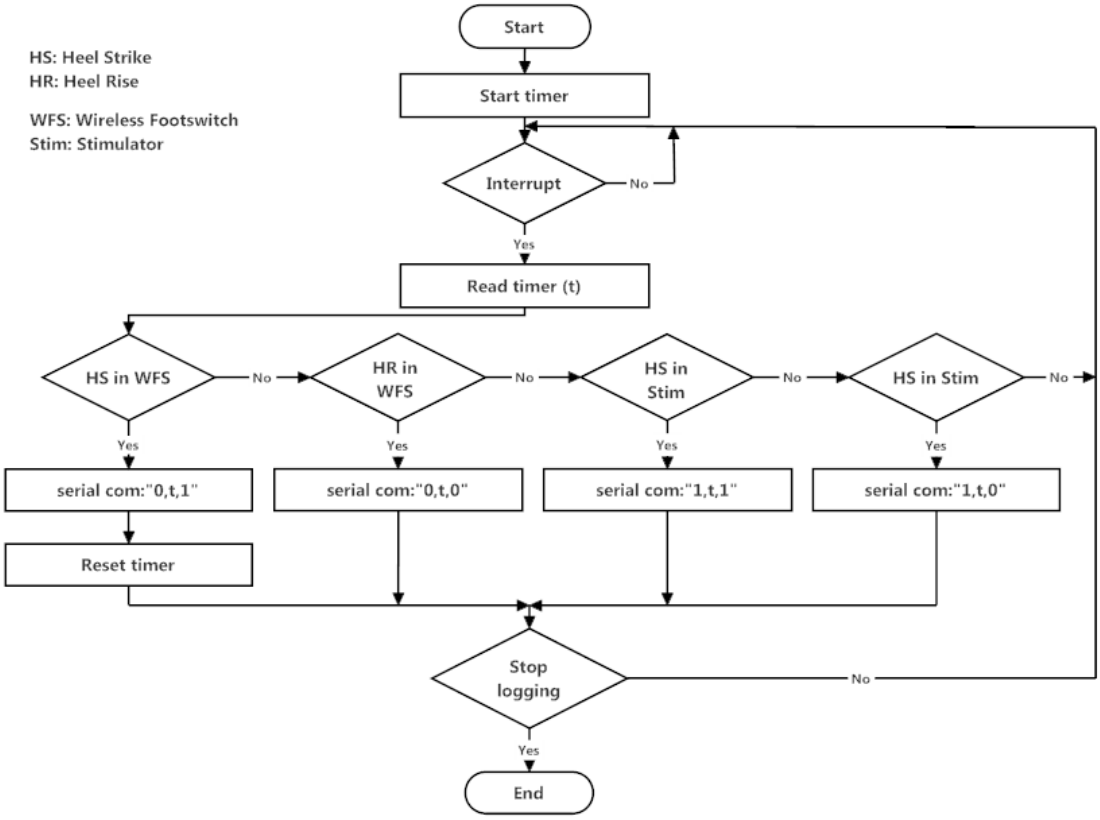


Figure 4.4: Data logger flowchart

The microcontroller writes a message to a serial communication port, at every change of either of the two signals, consisting of: source of interrupt (sensor or stimulator node), time value, and the direction of change (high or low). These values were fed to a character based RS232 terminal (HyperTerminal) on a portable computer that recorded the data in a text file. The data was sent from the microcontroller in a Comma-Separated Values (CSV) format as follow: "source of interrupt (one digit), time in milliseconds (up to 5 digits), direction of change". The following sequence is an example of recorded data of one step (heel strike on footswitch, heel strike on stimulator, heel rise on footswitch, heel rise on stimulator):

```
0,1918,1
1,23,1
0,336,0
1,361,0
```

The recorded data was processed off line using Matlab (R2007b) to estimate reliability and latency by comparing the two recorded signals. Latency was estimated by calculating the time between the event happening in the wireless footswitch and the time the same event occurs in the stimulator node within a single gait period. If no event

is recorded in the stimulator node signal within one gait period, it is considered as failed and the latency is given the value "-1". This allowed calculating latency of every transmission during the recording and estimating the reliability of transmissions. For instance, from the sequence given above, the reliability is 100% (two messages transmitted -> two messages received), and the latencies for the two transmissions are: 23ms and 25ms.

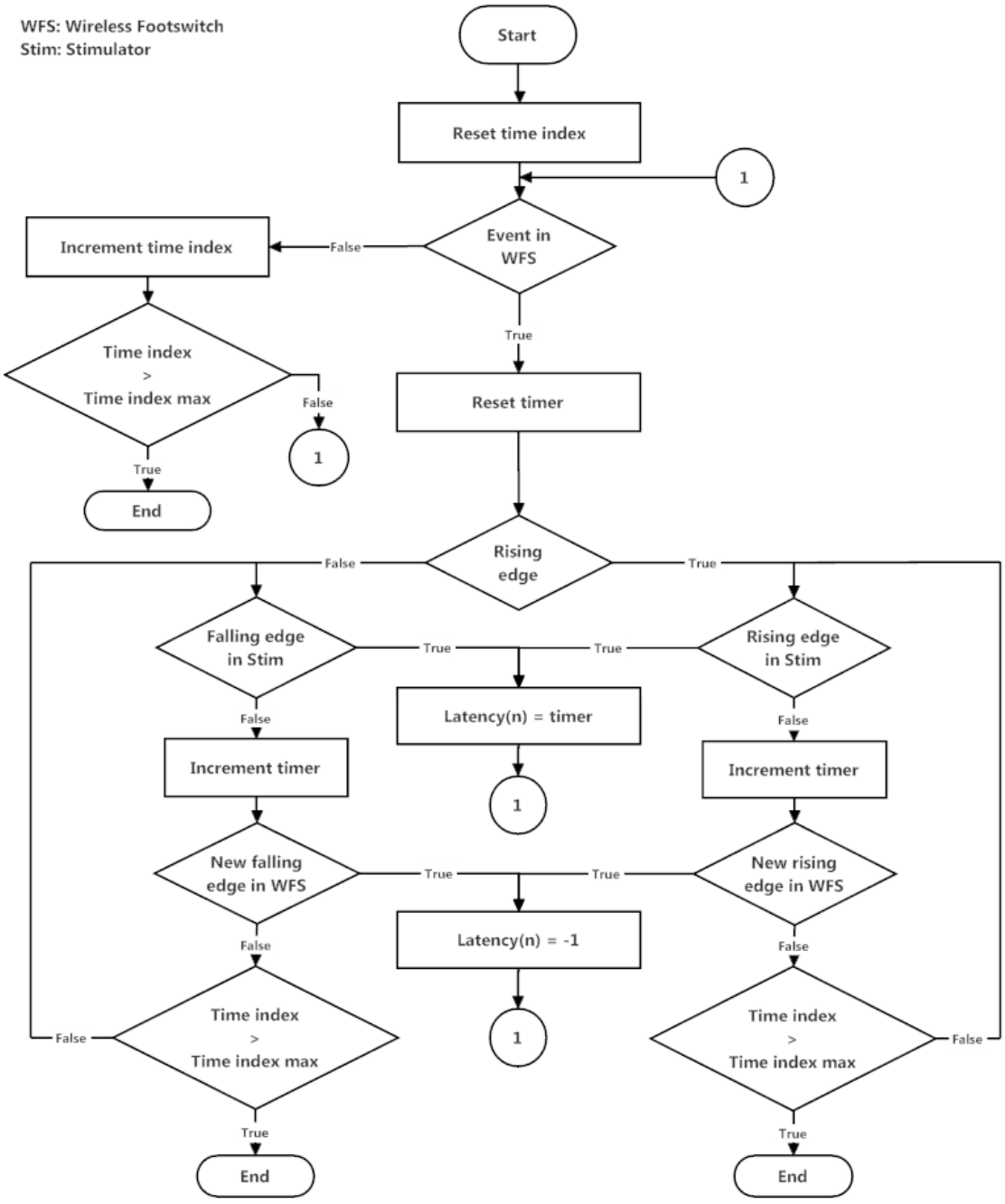


Figure 4.5: Flowchart of the latency estimation algorithm

Figure 4.5 represents a flowchart of this algorithm. Every failed transmission will be counted as two missed events by this algorithm due to the fact that this algorithm looks for a change in the received signal. For instance, if a heel rise message fails this causes the signal in the stimulator node to stay in the high logic level. When a heel strike is received, which normally causes a rising edge, it will not be visible on the signal since it is already high. As a result, all missed events will be an even number.

4.3.2 Bench testing

Reliability, latency, and power consumption were first estimated in laboratory conditions. The FSR in the wireless footswitch was replaced by a switching circuit that was supplied via a square wave from a frequency generator (GFG-8020H, Gw Instek). This allowed continuous periodic triggering and could be left running for as long as required. The output of this generator was connected to a voltage following circuit, as shown in Figure 4.6. The laboratory environment allows exposing the system to controlled interference sources separately (such as: Wi-Fi and Bluetooth).

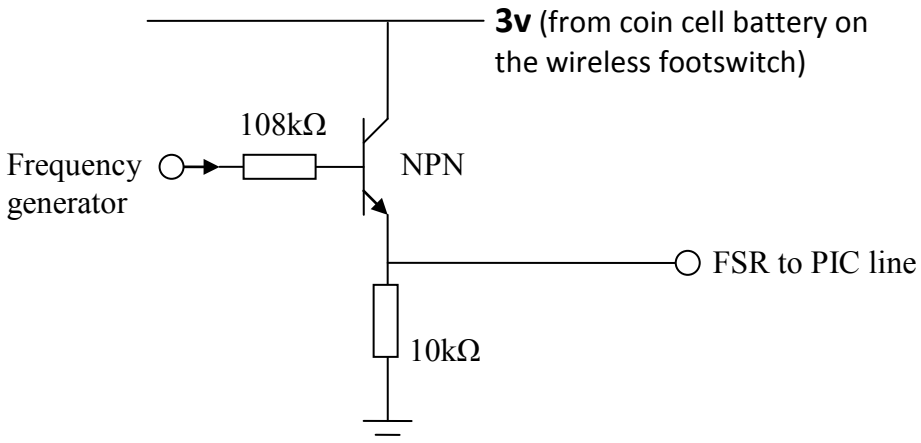


Figure 4.6: Voltage follower circuit used with a frequency generator to trigger the wireless footswitch for in-laboratory experiments

The system was exposed to various interference sources representative of those likely to be experienced in everyday use and occupying the same band of frequencies as ZigBee (2.4GHz). This included: Wi-Fi networks, Bluetooth networks, other ZigBee networks, and Microwave ovens.

4.3.2.1 Reliability and latency experiments

Reliability and latency were estimated at the same time by processing the data, recorded using the data logger, on Matlab (R2007b). As explained in section (4.3.1.4), the Matlab function generates an array of latency values which are used to generate graphs of latency values and distribution of latencies. It also calculates the number of failed transmissions which is used to estimate the reliability of the wireless system.

The system was exposed to various interference sources representative of those likely to be experienced in daily use and occupying the same band of frequencies as ZigBee (2.4GHz). This included: Wi-Fi networks, Bluetooth networks, other ZigBee networks, and Microwave ovens. All experiments except the one with microwave oven interference (see section 4.3.2.1.5) were run and stopped soon after they reached 10,000 transmissions (the exact values are given in Chapter 5), which is equivalent to the recommended daily number of steps for healthy adults. The daily number of steps for average people and patients is usually less than this value [101]. The frequency generator was set to 1.17Hz which is equivalent to an average fast gait rate as measured on three healthy volunteers. This results in a transmission rate of 2.34 transmissions per second. The experimental environment is shown in Figure 4.7.

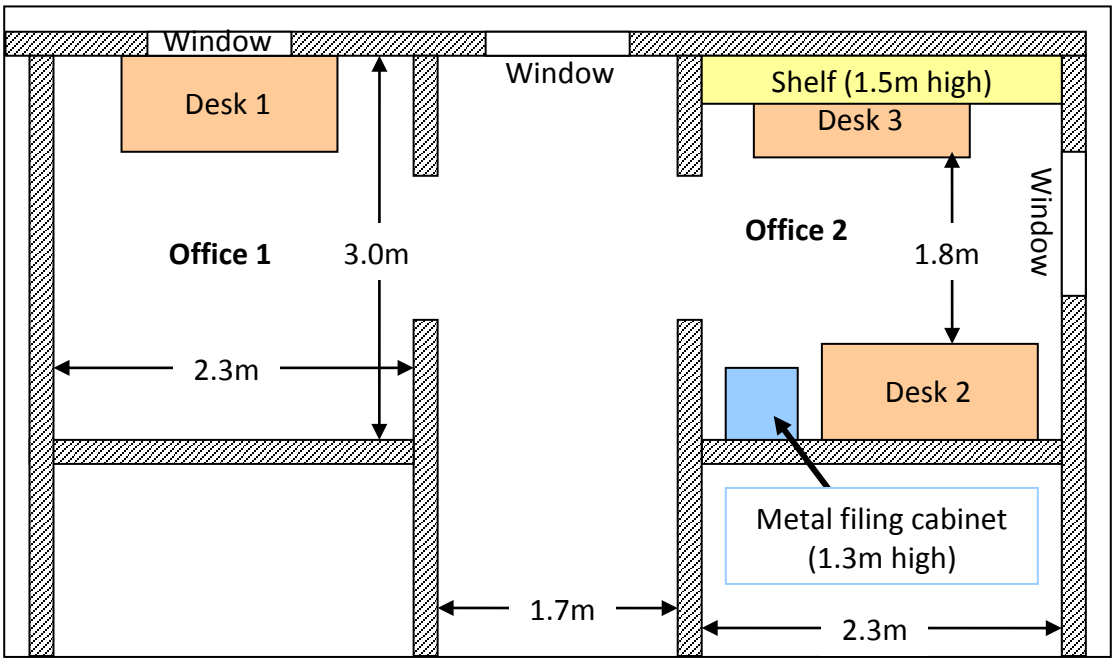


Figure 4.7: Diagram of the experimental environment for in-laboratory reliability and latency experiments

In all these experiments the wireless footswitch was powered with a coin cell battery (CR2430, Renata), and the stimulator node was also battery powered (PP3).

4.3.2.1.1 Interference free evaluation

First the system was tested in interference free environment by choosing a quiet ZigBee channel. This was achieved by setting the wireless module to scan all ZigBee channels and choose the quietest one. This was verified using a spectrum analyser (Wi-Spy 2.4x, MetaGeek) which shows low spectral activity in the chosen channel. The sensor node was put on an insole on the floor underneath desk 1 (Figure 4.7), which imitates putting the sensor in the shoe. The stimulator node was left on top of desk 1. This puts the stimulator at the same height as the waist of an adult where it is usually worn. The experiment was stopped soon after one hour and 12 minutes which is equivalent to 10,108 transmissions.

4.3.2.1.2 Evaluation with Wi-Fi interference

Wi-Fi interference was created by setting up a Wi-Fi network using an IEEE 802.11b router (DWL-900AP+, D-Link) set to stream data to a laptop (Satellite Pro A330, Toshiba) placed on desk 1. The Wi-Fi channel chosen was Wi-Fi 3 which overlaps with ZigBee channel 14 set on the experimental system. The data rate to and from the laptop was recorded using NetWorx (V 5.1.7). The experiment was repeated 12 times in order to test the system in different arrangements in terms of location of the Wi-Fi router to the wireless FES system and the data traffic on the Wi-Fi network. The two nodes of the wireless FES system were kept in the same configuration; stimulator on a desk and the sensor node underneath it on the floor on top of an insole. Trial 12 had exceptionally both nodes (stimulator and sensor) on a desk. Table 4.1 summarises the configuration of all trials and data rates. The aerial of the spectrum analyser was put next to the ZigBee module on the stimulator node and recorded spectrum activity for all trials.

Trial	Arrangement of devices	Average bit rate (Kbyte/s)	Maximum bit rate (Kbyte/s)
1	Wi-Fi Router in office 2 (next to the window). Wireless FES system in office 1.	<20 (low traffic)	<20
2	Same arrangement as trial 1.	129 (in) 4.82 (out)	216 (in) 59 (out)
3	Wi-Fi Router on the shelf in office 2. The wireless FES system in office 2.	<20 (low traffic)	<20
4	Same arrangement as trial 3.	123 (in) 4.24 (out)	270 (in) 73.4 (out)
5	Wi-Fi Router put on the floor 20cm from the sensor node (office 2).	114 (in) 3.81 (out)	217 (in) 20.9 (out)
6	Wi-Fi Router put on the floor 80cm from the sensor node (office 2).	130 (in) 4.57 (out)	224 (in) 413 (out)
7	Wi-Fi Router put on desk 2, 20cm from the stimulator node.	129 (in) 4.22 (out)	276 (in) 12.0 (out)
8	Wi-Fi Router put on desk 2 and slightly raised (15cm), 30cm from the stimulator node.	124 (in) 4.49 (out)	279 (in) 39.6 (out)
9	Wi-Fi Router put on a cardboard box next to the sensor node (in office 2), 30cm high (in a level between the two FES nodes).	110 (in) 3.21 (out)	217 (in) 40.5 (out)
10	Wi-Fi Router on the filing cabinet, 1m to the right relative to the stimulator node (office 2)	103 (in) 3.11 (out)	216 (in) 19.5 (out)
11	Wi-Fi Router on desk 3. Wireless FES system in office 2.	133 (in) 4.16 (out)	234 (in) 25.0 (out)
12	Wi-Fi router and the two FES nodes on desk 2. The router between the FES nodes (30cm from each).	118 (in) 4.06 (out)	252 (in) 37.7 (out)

Table 4.1: Arrangement of devices in the Wi-Fi interference experiment

4.3.2.1.3 Evaluation with Bluetooth interference

Bluetooth interference was created by streaming audio from a tablet PC (Archos 70) to a Bluetooth dongle (ACB10EU, Targus), plugged to a laptop placed on desk 1. The experiment was repeated three times to test different locations of the Bluetooth source related to the two nodes of the FES system. The arrangements are summarised in table 4.2. Spectrum activity of the 2.4GHz was recorded during all trials using the spectrum analyser which was located next to the stimulation node.

Trials	Arrangement of devices
1	The two FES nodes on desk 2 one metre apart. The Bluetooth source next to the sensor node (10cm).
2	The stimulator node on desk 2. The sensor node on an insole on the floor underneath desk 2. The Bluetooth source was left 10cm from the stimulator node on desk 2.
3	The two FES nodes were left in the same locations as trial 2. The Bluetooth source on desk 2, 80cm from stimulator node.

Table 4.2: Arrangement of devices (Bluetooth interference experiment)

4.3.2.1.4 Evaluation with ZigBee interference

The experiments also included tests on coexistence with another ZigBee network. This was done using two Telegesis development boards (ETRX3DVK). One of these boards was set to request reading a register on the other node periodically every 250ms. This resulted in two transmissions (one from each node) every 250ms. Transmission power on both nodes was set to maximum to cause the highest interference possible. The experiment was repeated four times with different arrangements. This is summarised in table 4.3. As with the previous experiments, the spectrum activity was recorded.

Trial	Arrangement of devices
1	The stimulator node on desk 2. The sensor node on the floor (on an insole) underneath desk 2. The coordinator of the interfering ZigBee network in office 1. The second interfering node on desk 2, 80cm away from stimulator node.
2	The two FES nodes and the coordinator node of the second network were kept in the same arrangement as trial 1. The second interfering node on a cardboard box (30cm high) underneath desk 2.
3	The two FES nodes and the coordinator node of the second network were kept in the same arrangement as trial 1. The second interfering node on desk 2, 5cm away from the stimulator node.
4	The two FES nodes and the coordinator node of the second network were kept in the same arrangement as trial 1. The second interfering node on the floor, 5cm from the sensor node.

Table 4.3: Arrangement of devices (ZigBee interference experiment)

4.3.2.1.5 Evaluation with microwave oven interference

A further experiment was made to evaluate system performance in the presence of interference from a 900W microwave oven (CE107B, Samsung). This is due to the fact that microwave ovens use the same band of frequencies as ZigBee (2.4GHz).

microwaves have a Faraday cage to contain waves inside the oven, however, leakage of these waves might occur which could interfere with wireless devices using the same band of frequencies [85]. Two trials were performed in this experiment each lasting for five minutes allowing a total of 780 transmissions. The microwave oven was set to full power in both trials and a glass of water was used as a heating load. The experiment was not left longer for safety reasons (water would reach very high temperatures and might evaporate completely if left for longer periods). In the first trial, the stimulator node was put behind the oven (both on a desk) and the sensor node put underneath the desk on top of an insole on the floor. In the second trial, the sensor node was kept in the same location and the stimulator node was left on top of the microwave oven.

4.3.2.1.6 Effects of loaded stimulation output:

Finally the system was tested while the stimulator node generated stimulation output into a load. The stimulation parameters were set to the default setting on the ODFS Pace (typical values recommended by clinicians in the National Clinical FES Centre).

4.3.2.2 Power consumption

As the device is battery powered, the power consumption needed to be investigated to identify the type of batteries that can be used and to minimise power required in order to maximise the battery life.

An experiment was designed to test the battery life of both the wireless footswitch and the stimulator node. In this experiment, an automated footswitch tester (see section 4.2.2.2.3) was used to press and release an FSR connected to the wireless footswitch. This causes the current to vary (i.e. changes power consumption), as it would do in real conditions, due to the fact that the current across the FSR depends on the resistivity which in turn depends on the pressure applied on the FSR. These experiments were performed in a laboratory at room temperature.

4.3.2.2.1 Wireless footswitch battery test

A coin cell (CR2430, Renata. Datasheet found in Appendix E) was used to power the wireless footswitch. The stimulator node was powered using a power supply to ensure no interruption of the experiment due to power cut on that node. The wireless footswitch code was changed to include an event counter and saved the count to the integrated memory of the microcontroller (EEPROM). At the start of the experiment,

the counter was reset to zero and a fresh battery was used. The voltage of the electric motor of the automated footswitch tester was set to 7.9v which results in a rate of 35 steps per minute (~1.17 transmission per second). The experiment was left running until the battery of the footswitch failed.

The battery voltage was logged throughout the whole experiment at a sampling rate of one sample every 30min (2 samples/h). The logging device was a USB ADC11/10 (Pico technology, UK).

4.3.2.2.2 Wireless stimulator node battery test

This experiment was designed to measure the battery life on the stimulator node with stimulation on. A stimulation load therefore was connected to the stimulation output and set the stimulation parameters to the default values for drop foot stimulation. The battery used was an alkaline PP3 9v (Duracell PROCELL Professional 9v) which is recommended by OML for ODFS Pace users. The footswitch node was powered using a power supply and the footswitch tester was set to the same rate as the previous experiment. During this experiment, the voltage of the battery was logged at a rate of 6 samples per hour (i.e. one sample every 10 minutes). In addition, the counter on the footswitch was used to count the number of events transmitted. The experiment was stopped when the battery failed.

4.3.2.2.3 Automated Footswitch tester

The automated footswitch tester emulates walking patterns by pressing the footswitch and releasing it periodically to trigger the footswitch (Figure 4.8). It is composed of an electric motor which rotates three branches. Each branch ends with a wheel that is designed to hit a shoe sole fitted with a FSR. The FSR is connected via a lead to the wireless footswitch. The speed of rotation of the motor is variable with its input voltage. Hence a variable voltage power supply is used to power this motor to control the speed. This device was designed and built by a Clinical Scientist trainee (D. Nolan, Department of Clinical Science and Engineering, Salisbury District Hospital, UK).

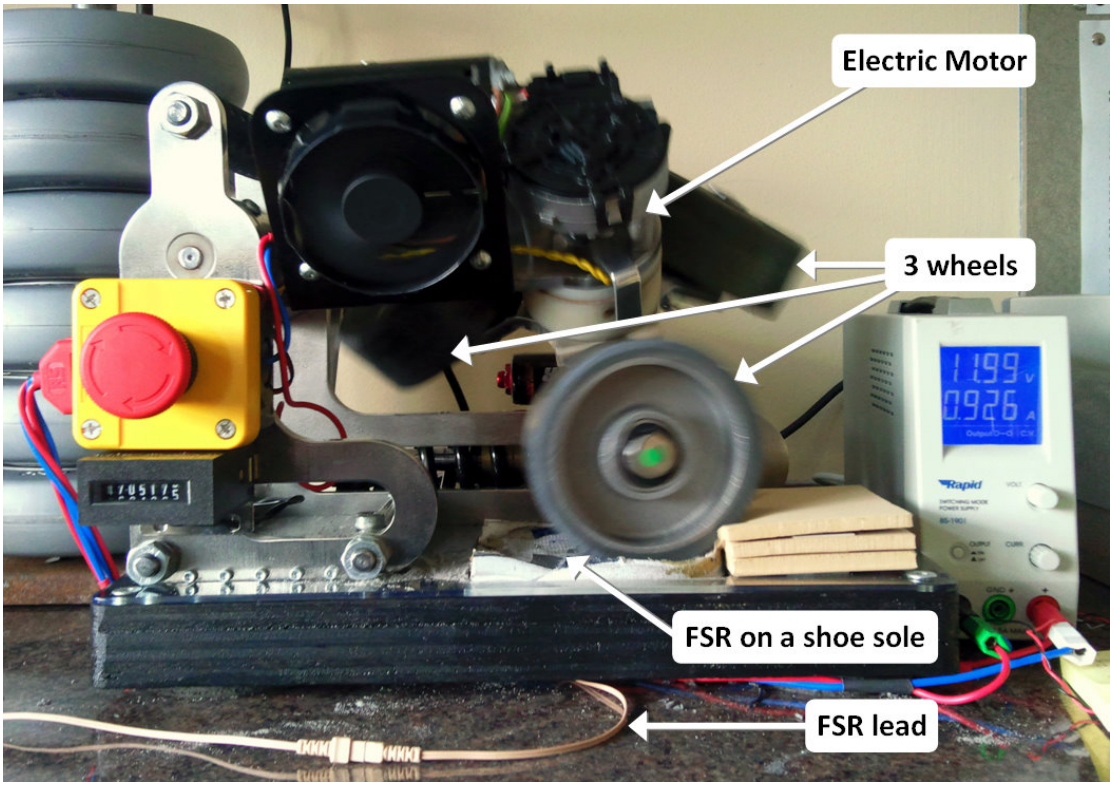


Figure 4.8: Automated footswitch tester used in the power consumption experiment

4.3.3 Real world condition evaluation

4.3.3.1 Evaluation with healthy volunteers

This experiment was intended to estimate the reliability and latency of the wireless system while worn by healthy volunteers. Each volunteer was asked to follow an identical route that included a mixture of indoor and outdoor environments around Salisbury District Hospital (Salisbury, UK). The selected walking route included exposure to different wireless technologies, mainly Wi-Fi networks and cordless telephones which were identified independently using the spectrum analyser (Wi-Spy 2.4x, MetaGeek). Additionally, the route included walking through wide open spaces (a car park) which tested the behaviour of the system in the absence of significant reflections. Fifty two Wi-Fi networks were identified along the defined route using Wi-Spy. Figure 4.9 represents the average and maximum spectral activity of each ZigBee channel in the 2.4GHz band. This was recorded using Chanalyzer 3.4 (MetaGeek) during one of the walks.

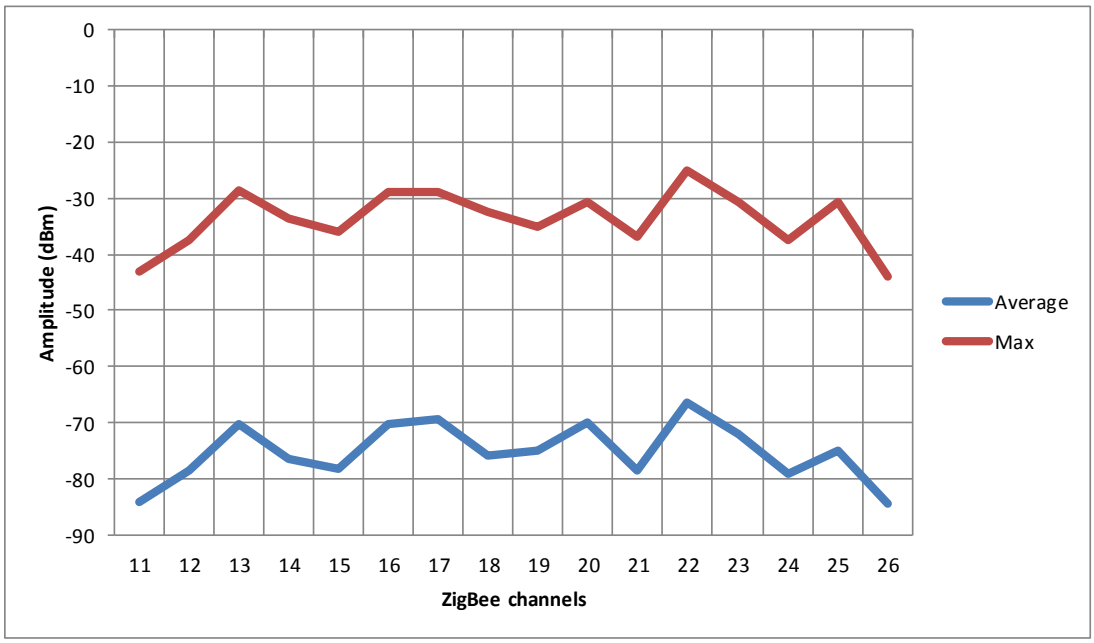


Figure 4.9: Spectrum activity of the 2.4 GHz band recorded during one of the walks for the real world condition evaluation (using Chanalyzer 3.4)

Six healthy volunteers were recruited for this experiment. Participants were asked to wear the insole that incorporates the wireless footswitch and to put the stimulator node in their pocket. The data logger and laptop were put in a bag carried by the participant. The sounder on the stimulator node (audible during stimulation burst) was enabled to be able to hear whether the device is stimulating or not. The author was walking with volunteers throughout the whole route to guide each person along the same route and to note any missed stimulation, identified from the audible feedback of the device. This experiment did not involve stimulation of the participants and therefore, the stimulation output was left floating. As a result, NHS ethical approval was not required. The wireless modules used were certified by the Federal Communications Commission (FCC) which ensures they present no risk to other devices. Spectral activity of the 2.4GHz band was recorded for each trial using Wi-Spy.

4.3.3.2 Evaluation on patients

The previous experiments were followed by patients' trial of the wireless drop foot system. This trial was conducted by Odstock Medical Ltd (OML, UK) which manufactures and commercialises the ODFS Pace. OML is sponsoring this project and is interested in the outcome of this research for future products.

Twenty two OML patients were recruited for this trial. All participants already use the ODFS Pace for drop foot and known regular users. The aim of this trial was to evaluate the system with a variety of users, therefore, a diverse group of volunteers was selected including both female and male, stroke and MS patients, and small size to large size users. Users whose cognitive ability may result in significant difficulty using the system were excluded.

Three clinicians from OML were responsible for setting up the wireless system and explaining the function of the device to the participants. Participants were given the device to use for daily activities and were given follow up appointments after one month. Contact detail was given to them to report any difficulties or problems with the system. After the one month period, patients were given another two months appointment.

This trial is aimed at evaluating the system in real conditions with patients. Some of the required outcomes are: how patients feel about using a wireless system instead of a wired one, how reliable the system is, and how long batteries last. The trial is still being undertaken at the time this thesis was being written and therefore only initial results will be reported in the next chapter.

4.4 Wireless three-channel stimulator testing

The second part of this research was to investigate the feasibility of a distributed FES system of a three-channel stimulator. This system was designed to correct drop foot and assist reciprocal arm swing while walking, and to assist reaching and grasping when standing or sitting if an attempt to reach is detected. The system consists of three wireless stimulators (same hardware described in 4.3.1.3) and one wireless footswitch (same hardware described in 4.3.1.2).

4.4.1 Prototype

The proposed wireless three-channel stimulator consists of three wireless stimulators and one wireless footswitch. The hardware of the wireless stimulators is exactly the same as the wireless drop foot stimulator (first prototype). The wireless footswitch hardware is also the same as the first prototype. The firmware of these nodes was modified to include the new functionalities. This includes making use of the accelerometer in the wireless footswitch and two of the wireless stimulators (located in

the expansion board). The system is designed to be worn as represented in Figure 4.10. Channel 1 is the drop foot stimulation channel. Channel 2 is the triceps brachii stimulation channel used for both reciprocal arm swing and elbow extension (when reaching). Channel 3 is the wrist/fingers extensor stimulation channel used to open the hand when reaching.

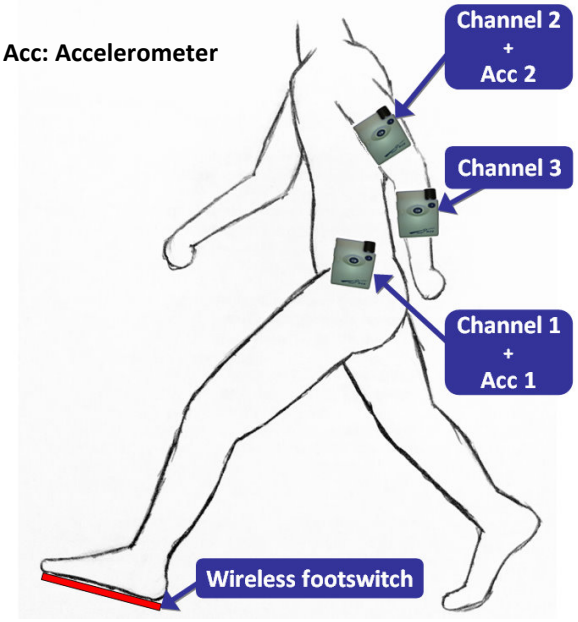


Figure 4.10: Representation of how the wireless 3-channel system is worn

4.4.1.1 Wireless footswitch

The built in accelerometer was used to detect whether the user is walking or not. This information was combined with the footswitch algorithm to transmit heel events only when walking is detected. This has the advantage of eliminating false positive triggering as found by patients when they transfer weight from one leg to the other as found by Pappas et al. [57]. The threshold of detection of walking was set to 312.5mG (any acceleration above this value enables walking mode if not enabled already). The threshold for detecting the stationary mode is set to 125mG. Enabling the stationary mode is only done when acceleration is below the threshold for a period more than 3s. The threshold values and the 3s period were defined after a series of experiments on an able-bodied subject. The footswitch algorithm is performed all the time even when the stationary mode is detected, only transmission of events is enabled or disabled. The flowchart of the detection of modes in the wireless footswitch is given in Figure 4.11.

When a heel event is detected, while the footswitch is in stationary mode, the device transmits this event as soon as it switches to walking mode. This enables the device to be reliable even when the user starts walking slowly (low acceleration at the start).

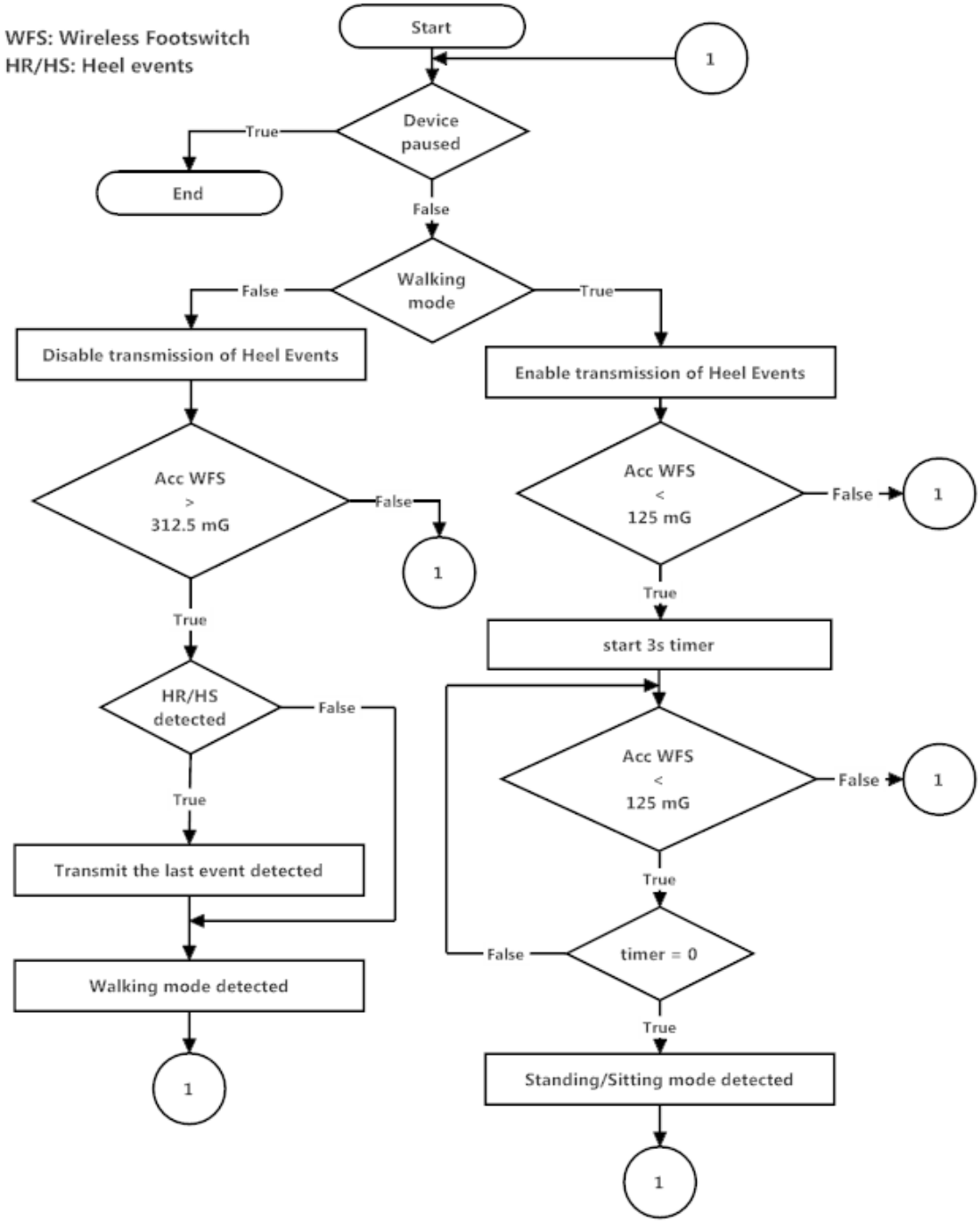


Figure 4.11: Flowchart of walking and stationary modes detection in the wireless footswitch

4.4.1.2 Wireless stimulator

The accelerometer built in channel 1 is used to detect if the user is walking or not. This is achieved, similarly to the footswitch, by monitoring the acceleration level and

comparing it to two threshold values; 625mG for activity and 312.5mG for inactivity. These values also were defined after experiments performed on an able-bodied subject. The following flowchart (Figure 4.12) represents how walking detection algorithm is performed.

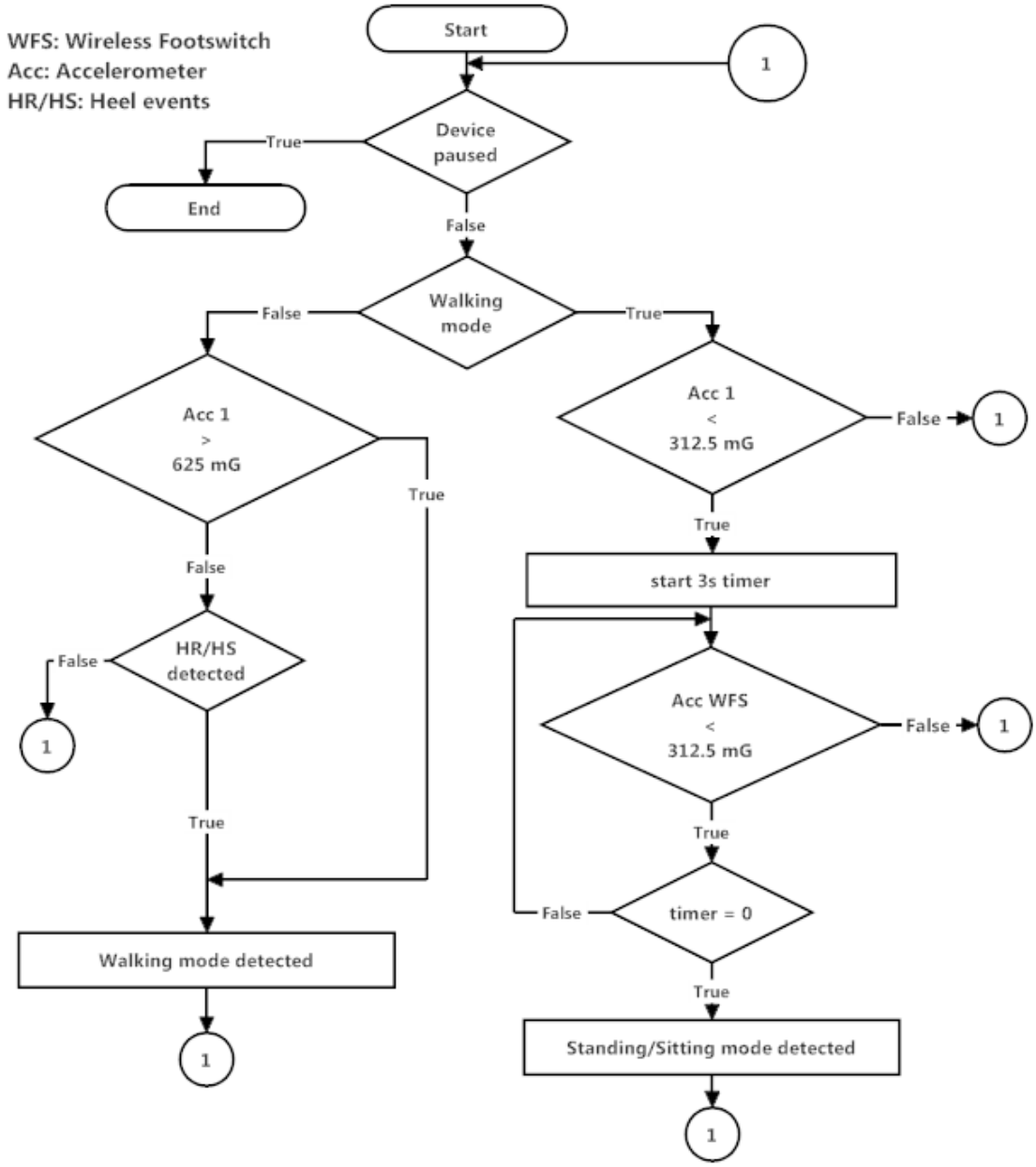


Figure 4.12: Flowchart of walking and standing/sitting modes detection in stimulation channel 1

Switching to walking mode is done when acceleration exceeds the activity threshold, and switching to standing/sitting mode is done if acceleration stays below the inactivity threshold for over 3s. The system is also designed to switch to walking mode if a heel event is received.

The accelerometer in the triceps channel is used as a tilt sensor to trigger reaching stimulation. Activity and inactivity threshold can be set via the menu of the ODFS Pace (modified by the author for the occasion). This enables setting the tilting threshold individually to patients. Triggering is done by constantly monitoring one component (X axis) of the DC value of acceleration. The X axis of the accelerometer as shown in Figure 4.13 would be parallel to the ground level when the arm is in the neutral position. So the value in the neutral position is 0mG and increases when the shoulder is flexed (Figure 4.13 shows this movement). This represents mainly acceleration due to gravity if the movement is not too sudden. For this reasons, the triceps stimulator (channel 2) has to be worn on the upper arm as shown in Figure 4.13.

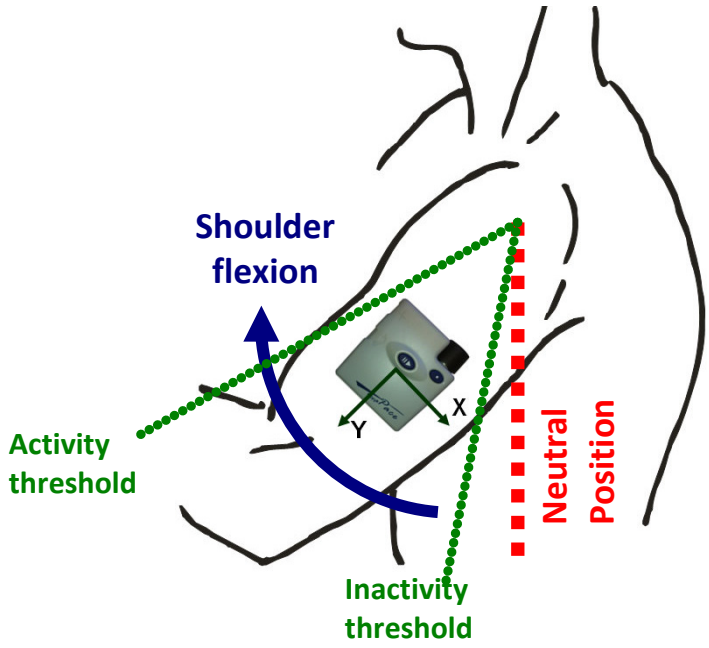


Figure 4.13: Triceps stimulator (channel 2) position with accelerometer axis X and Y

Relying only on the X axis has the advantage of triggering only when the shoulder is flexed and not when it is abducted (arm moving away from the body in the frontal plane). Stimulation starts if the value monitored exceeds the threshold (activity threshold). Stimulation can be stopped either if it times out, or by moving the arm back to the neutral position which means that the monitored value on the X axis is below the threshold (inactivity threshold). In order to avoid triggering stimulation when the device is tapped (tapping creates high acceleration values on all axis for a short period), the accelerometer takes another reading after a period of 200ms and compares it to the activity threshold. Only after the DC acceleration value exceeds the threshold in the two

readings that the system detects a reaching attempt and therefore generates stimulation. Figure 4.14 summarises these steps which are performed in the triceps channel (channel 2).

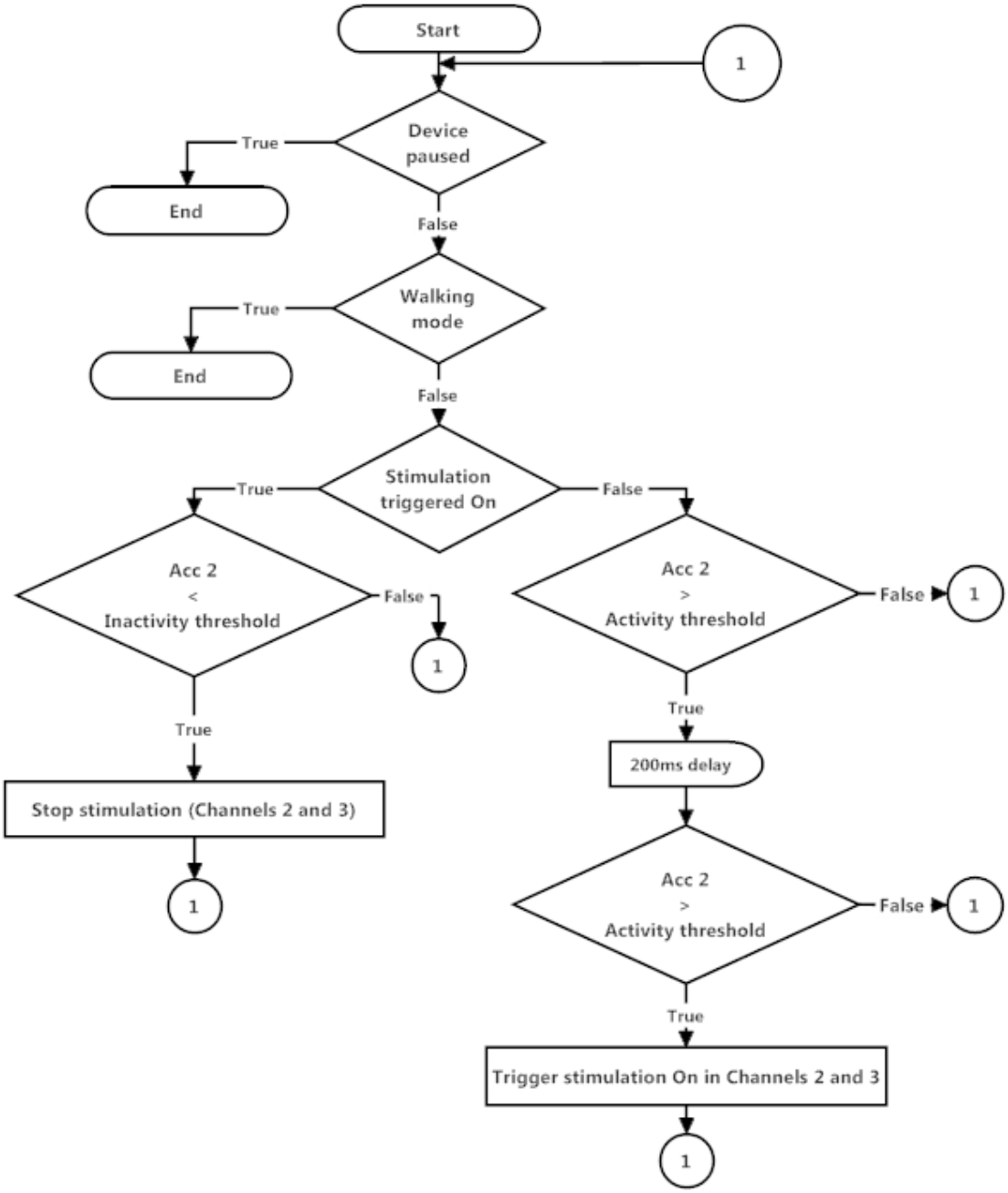


Figure 4.14: Flowchart of stimulation triggering of channels 2 and 3

For experimental purposes, expansion boards on both the drop foot and the triceps channels have two digital outputs. The first one is the stimulation triggering signal which is set low when stimulation is on. The second output represents the events detected by the accelerometer. This output is set high when inactivity is detected

(standing/sitting mode or stop reaching are detected), and set low when activity is detected (walking mode or reaching attempt are detected). In the third stimulation channel, one digital output is set to represent the stimulation trigger of channel 3.

4.4.1.3 Control Strategy

The system is designed to enable only channels 1 and 2 when walking is detected. These two channels are triggered at the same time using the wireless footswitch. When the system detects that the user is not walking, it enables channels 2 and 3 for reaching stimulation. Stimulation in this case is triggered using accelerometer 2 (built in channel 2). A flowchart summarising the control strategy is given in Figure 4.15.

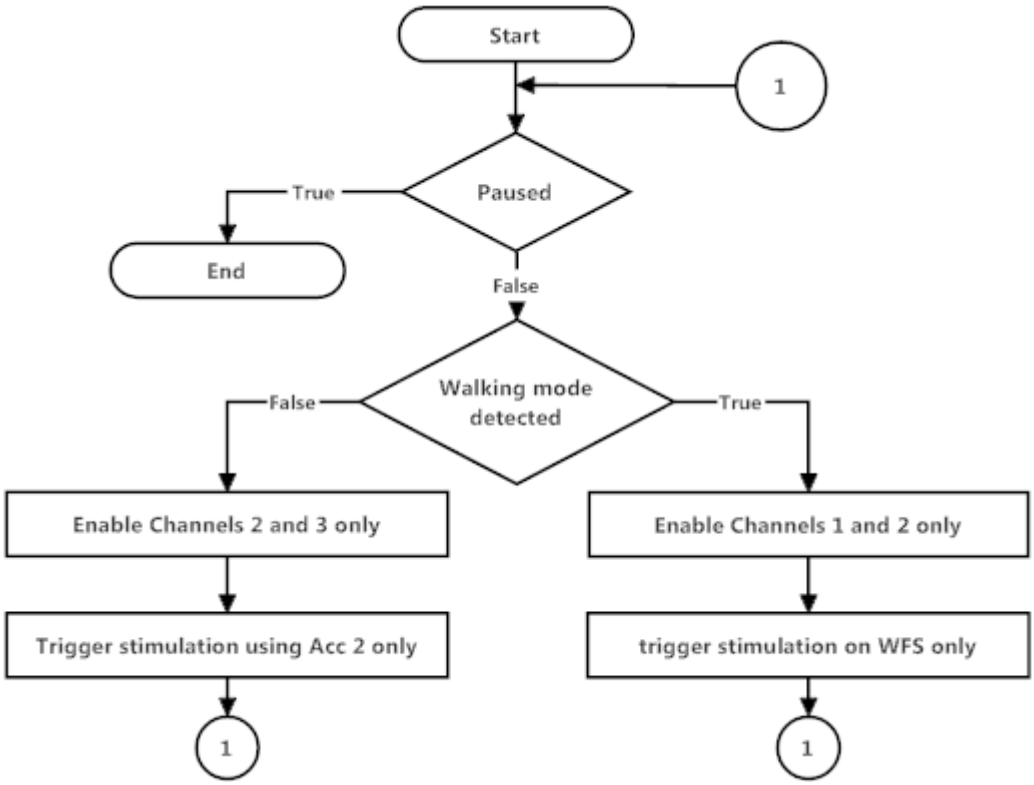


Figure 4.15: Flowchart of the control strategy of the proposed three-channel stimulator

The system performs walk detection in the drop foot stimulator (channel 1) which relies on the built-in accelerometer and the wireless footswitch to make a decision on what mode (walking or standing/sitting) should be enabled. Once the decision is made, the other nodes are notified by channel 1 to enable their predefined operations respective to the detected mode. A summary of operations of the four nodes is given in Table 4.4.

Node	Functions
Channel 1	▪ Detects whether the user is walking or not (using built in accelerometer (ACC1) and wireless footswitch). As described in Figure 4.12. ▪ Wirelessly notify the other two channels on any change of the operation mode (walking or standing/Sitting). ▪ Trigger drop foot stimulation on heel events received from the wireless footswitch and forwards them to channel 2 stimulator.
Channel 2	▪ Enables triggering stimulation on heel events when notified, by channel 1, to switch to walking mode and disables triggering on the built in Acc 2. ▪ When notified to switch to standing/sitting mode, it enables triggering stimulation on ACC 2 (Figure 4.14) and forwards detected accelerometer events to channel 3.
Channel 3	▪ It disables stimulation when notified to switch to walking mode after completing the stimulation cycle if notification received while stimulating. ▪ When notified to switch to stationary mode, it triggers stimulation on received accelerometer events from channel 2.
Wireless footswitch	▪ Monitors the FSR to detect heel events. ▪ Monitors the built in accelerometer to identify whether the user is walking or not. ▪ Enables transmission of heel events to channel 1 only if walking is detected as represented in Figure 4.11.

Table 4.4: Summary of operation of the four nodes forming the three channel system

4.4.2 System evaluation

The first prototype was developed to test the concept of a wireless FES system. This second part of the project was aimed at testing the concept of a distributed FES system for a specific three-channel FES application. This involved a control strategy that enables automated control of coordinated movements. This system is required to be operationally reliable and repeatable. Hence two experiments were designed to evaluate the system. the proposed FES applications (drop foot, reciprocal arm swing, and reaching stimulation) are comprehensively demonstrated to be beneficial for patients [18,25,28], so these experiments will not focus on this but on demonstrating that the three applications can be included in one system that enables/disables them automatically when needed. Although the work on the second prototype involved designing detection methods using an accelerometer, this project does not test the effectiveness of accelerometers in triggering reaching stimulation.

The first experiment involved healthy volunteers only without applying stimulation. The second one was performed on a patient with hemiplegia (stroke patient) to evaluate the system in real conditions and to identify any areas for improvement.

4.4.2.1 Healthy Volunteers

This experiment was conducted to evaluate the operational reliability and repeatability of the system for single subjects and to determine subject to subject reproducibility. The experimental protocol was designed to include a combination of tasks which trigger all the events that the system is able to detect.

Only healthy volunteers were recruited in this study with the output of the stimulators being recorded and not applied on participants. The study was performed in a gait analysis laboratory with two video cameras and an analogue signal acquisition system that enables synchronisation of recorded signals with the video signal. Seven digital signals were recorded: FSR loaded/unloaded, walk detection in the wireless footswitch, walk detection signal in channel 1, reaching attempt detection signal channel 1 triggering signal, channel 2 triggering signal, and channel 3 triggering signal.

The two video cameras captured video from two views while the volunteer performed the study tasks. This allowed capturing all of the events that trigger/stop stimulation to be assessed during data analysis.

4.4.2.1.1 Procedure

The channel 2 stimulator was worn on the arm in a set orientation, as explained in section (4.4.1.2). The wireless footswitch was placed in an insole which is worn in the shoe. The author assisted participants in applying the sensor in the correct orientation.

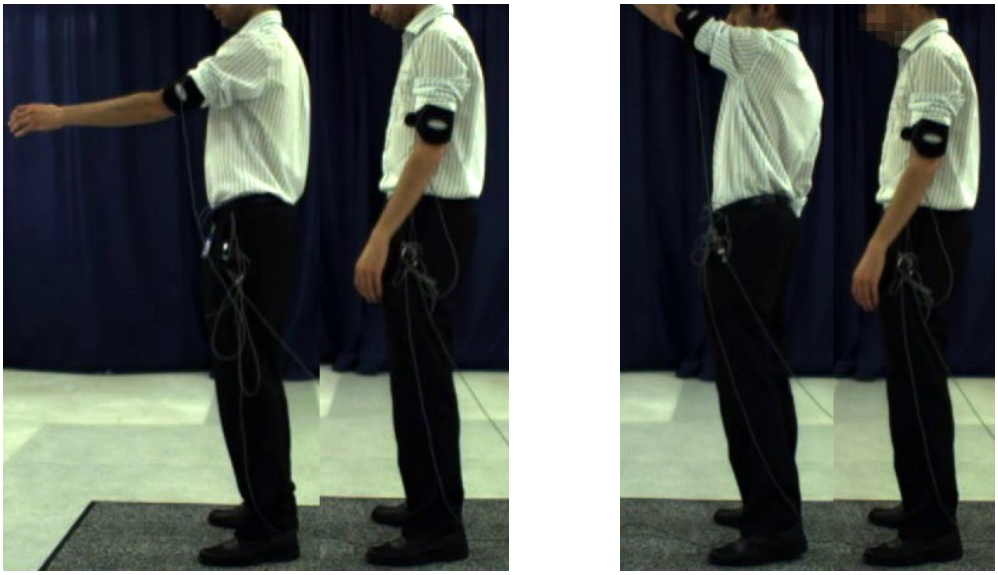
Eleven volunteers were recruited for this experiment. The experiment was designed to test all the situations that the system is designed to detect. The following tasks include these situations:

1) Walk 10 meters, turn around without stopping, walk back and stop half way.
2) Reach forward four times; The first two reaching movements were by flexing the shoulder forward to an angle below 90 degrees, and the last two were reaching up by flexing the shoulder by angles over 90 degrees as illustrated in Figure 4.16 (a and b). The reaching sequence had to be triggered for at least two seconds in order to be counted as complete by the

system. A sounder was enabled on channel 2 for two seconds to help volunteers follow the test protocol.

3) Transfer weight from one leg to the other while standing as seen in Figure 4.17.

4) Walk back to the starting point.



a) Reaching by shoulder flexion angles less than 90º **b) Reaching up by shoulder flexion over 90º**

Figure 4.16: Illustration of how volunteers were asked to enable reaching movement

Figure 4.17: Illustration of how volunteers were asked to shift weight from one side to the other

The experiment did not include stimulation at any point. It only involved collection of video and the seven signals mentioned in the previous section.

In order to verify measurement repeatability, the experiment was repeated 30 times with a single subject.

4.4.2.1.2 Evaluation of results

The recorded signals were plotted using Matlab for analysis alongside the recorded video. In addition, a Matlab function was created to generate predicted stimulation triggering of the three channels to be compared to the recorded one. This provides an objective way to evaluate the system. The function uses the recorded sensor data (four signals: FSR Loaded/Unloaded, walk detection in the wireless footswitch, walk detection in channel 1, and reaching attempt detection) to generate the three triggering signals for the three channels. This is done based on the same decision rules (explained in section 4.4.1) of the prototype. The function compares each recorded stimulation trigger to the respective predicted signal and counts any false positive event (event appearing on the recorded one and not on the prediction), and any false negative event (event missed in the recorded signal which is predicted to occur). This is achieved by counting the number of events in the recorded signal after every predicted event until a new predicted event or the end of data. Figure 4.18 represents a flow chart of the comparison function.

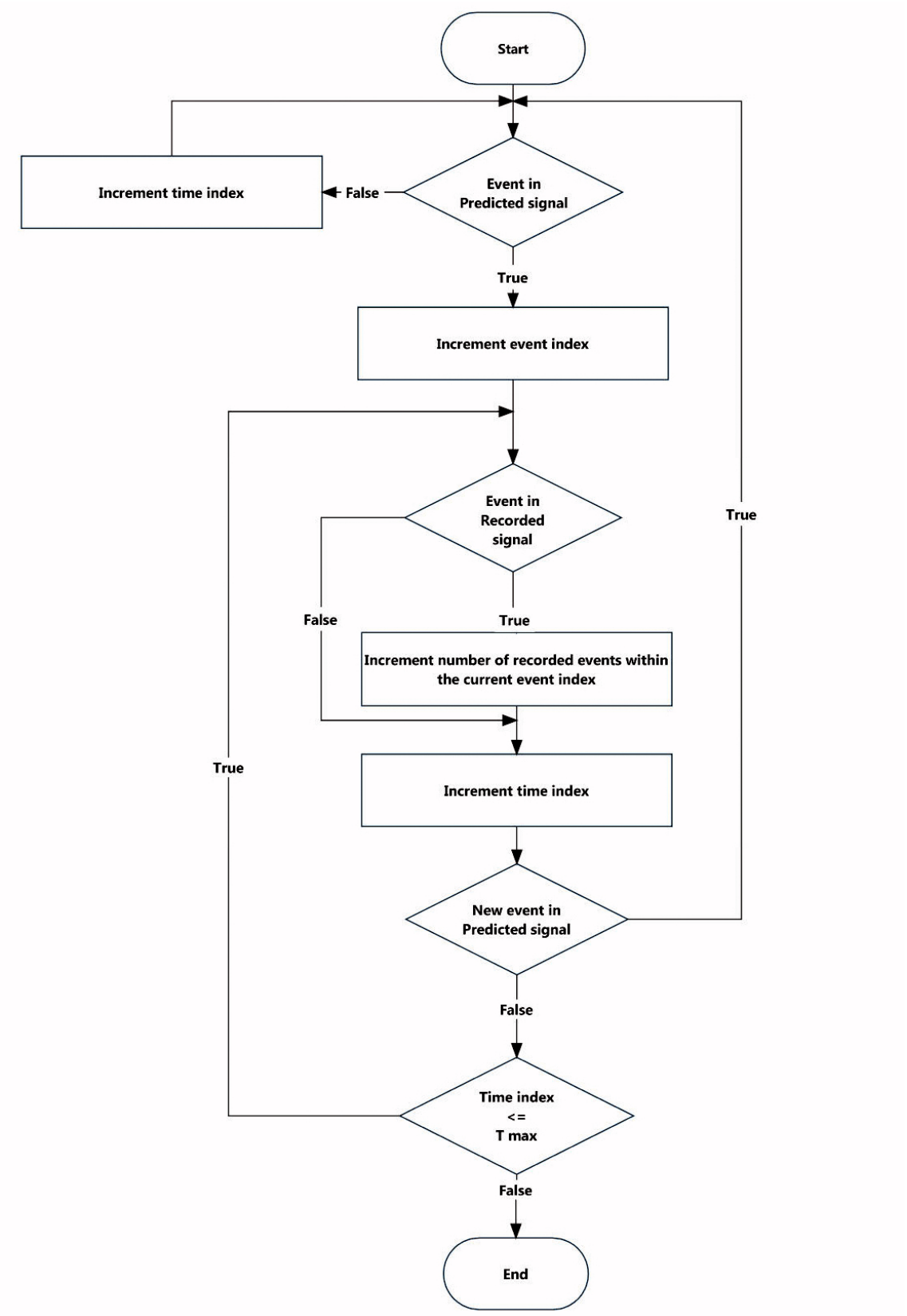


Figure 4.18: Flowchart of the Matlab function used to compare recorded stimulation triggering of the three channels with the predicted equivalent

4.4.2.2 Case study experiment

A patient with hemiplegia was recruited for this case study. The patient is an ODFS Pace user for drop foot and has impairment in the upper limb (on the same side as the drop foot). This patient was identified and contacted by an OML clinician who was present during the experiment to set up the stimulation parameters. Following advice from Salisbury office of the South West Research Design Service (SW RDS), NHS ethical approval was not required since the experiment does not involve NHS patients, NHS staff, or NHS facilities (Appendix A). An ethical approval was granted through Bournemouth University (Appendix B). Moreover, the stimulation output of the devices used was tested in OML (appendix N).

The experiment took place in the Gait Laboratory in Salisbury District Hospital, Salisbury, UK (run by OML). Using the same protocol as the experiment with healthy volunteers, seven digital signals were recorded and synchronised with two video cameras. In addition, the same prototype was used with the exception that in this case, stimulation was applied to the patient.

4.4.2.2.1 Procedure

The experiment consisted of two trials. The first one involved walking and reaching while standing. The second took place with the participant sat on a chair in front of a table and involved reaching for an object on the table. The configuration of the experiment is given in Figure 4.19.

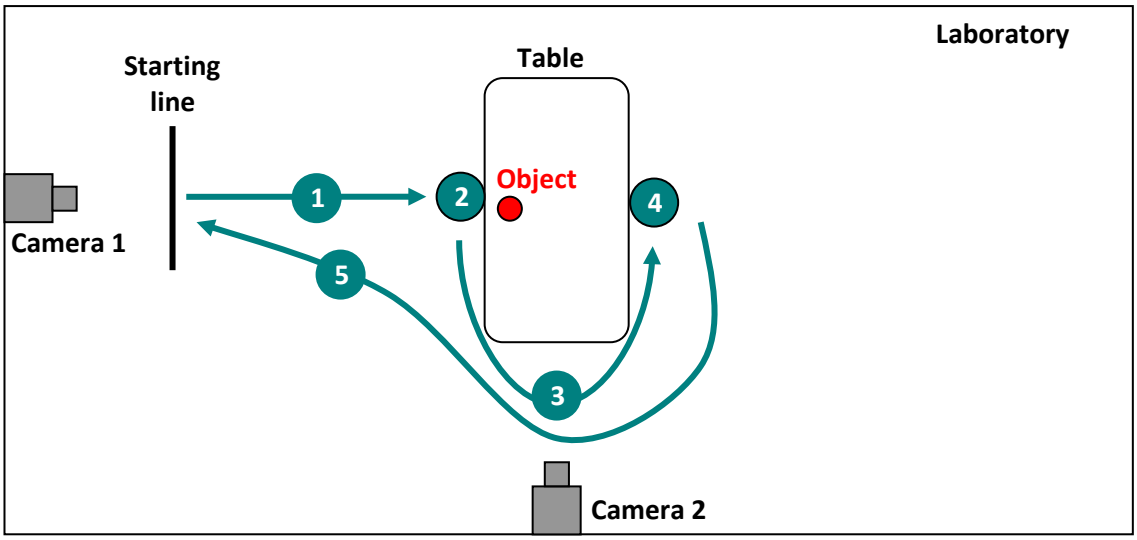


Figure 4.19: Setup of the first trial of the case study experiment

The patient was asked to perform the following tasks in the first trial:

1) Walk from the starting line and stop next to the table.
2) Reach and grab an object (empty tin can) with the impaired arm.
3) Walk around the table while holding the object in the hand.
4) Stop on the other side of the table and reach to release the object on the table.
5) Walk back to the starting line.

In the second trial, the patient was asked to reach and hold the object on the table while sitting. Then, reaching again to release the object back on the table. This was done to investigate the system in the two possibilities for reaching i.e. both while standing and while sitting.

4.5 Summary

This chapter described the experimental methods designed for this research project. As explained, the experiments were performed in two stages. The first stage was when testing the concept of a wireless FES system, for which a single channel drop foot system was designed and built. This first prototype was first tested in laboratory conditions to evaluate the reliability, latency and power consumption. This was followed by real world conditions involving healthy volunteers first and then patients. The second stage involved investigating the feasibility of a wireless distributed multi-channel FES system. This was verified by developing a three-channel FES system for drop foot and arm swing stimulation when walking, and reaching stimulation when stationary. In order to evaluate this system, experiments have been designed to test the system in real world conditions with healthy volunteers initially followed by a case study with one stroke patient.

This chapter described the two prototypes used for this research and the data logging device designed and built to perform some of the experiments. Data processing and analysis methods were also explained. The results of these experiments are given in the following chapter.

Chapter 5 - Experimental Results

5.1 Introduction

This chapter presents results of the experiments explained in Chapter 4. The results are arranged in two main sections. The first part describes the results obtained from experiments on the wireless drop foot FES system. In addition, it includes results of the experiments on dorsiflexion timing and the effect of delayed stimulation. The second section describes the experimental results on the wireless distributed three-channel stimulator.

5.2 Defining latency specification

5.2.1 Dorsiflexion timing experiment

This experiment was designed to investigate the time between heel rise and start of contraction of the tibialis anterior, and the time between heel strike and the finish of the activity of the tibialis anterior muscle. This was performed on unimpaired subjects in order to estimate an average period between heel events and activation/deactivation of tibialis anterior in an unimpaired walking gait.

As explained in Chapter 4, data from each step recorded was arranged in two periods; from heel rise to heel strike (simplified to swing), and from heel strike to heel rise (simplified to stance). The swing period data was normalised and rectified, and averaged with the other swing periods from the same trial (same walking speed from one volunteer at a time). This was done to reduce noise in the EMG signal. The same was done for the stance period data. The resulting data was represented in graphs of EMG activity during each gait phase which are given in Appendix F.

The first observation was the variability of the EMG signal from the four participants in this experiment. It was noticed that there are different shapes and patterns in the EMG signal between volunteers. This could be explained by the fact that each volunteer has slightly different patterns in their walking. This influenced timing and intensity of the tibialis anterior contraction.

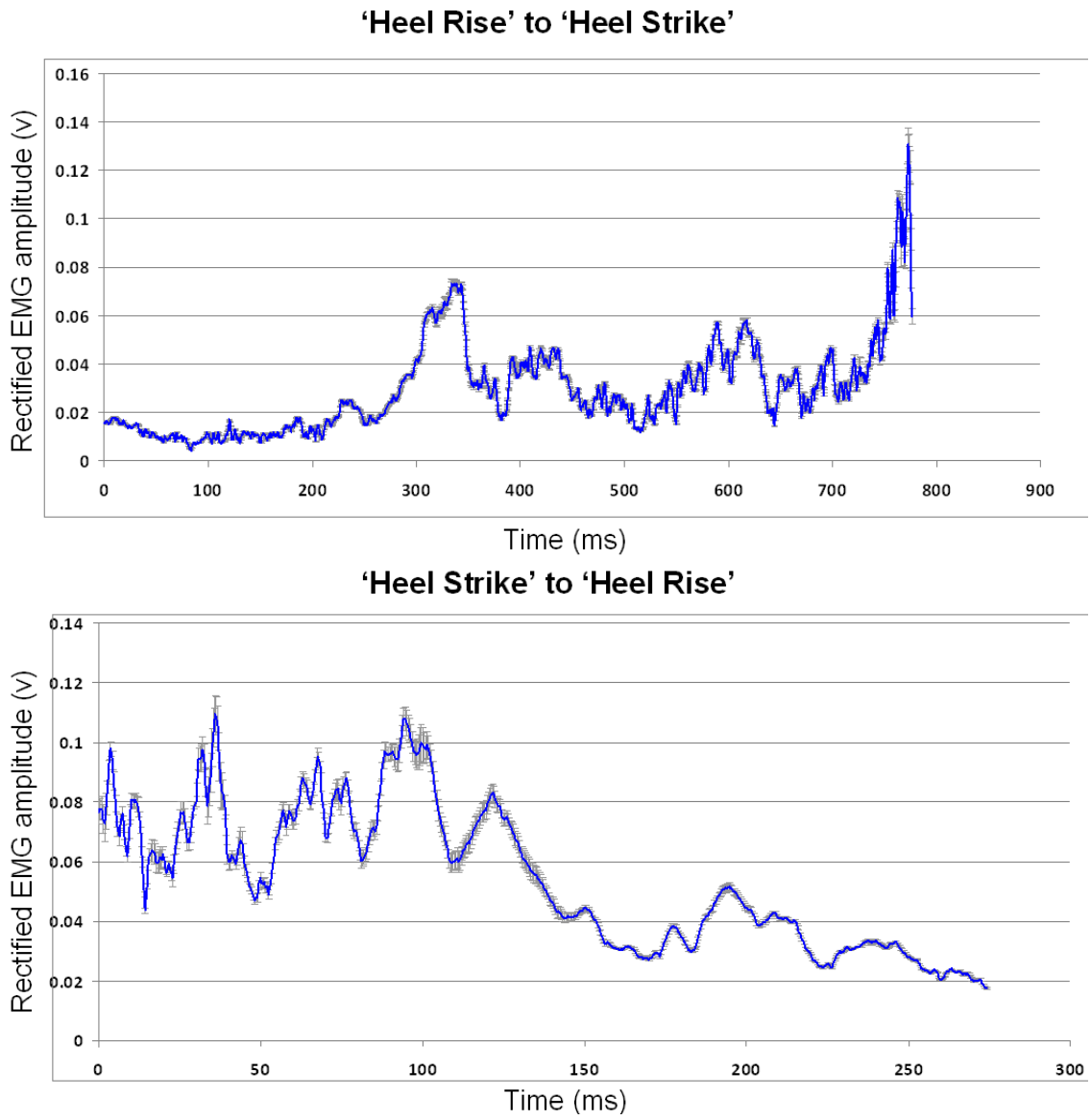


Figure 5.1: Rectified EMG signal of the tibialis anterior during a gait cycle (volunteer 1 – normal walking speed)

Volunteer 1 has a clear inactivity period after heel rise of more than 200ms at normal walking speed, as shown in Figure 5.1, as well as the other two walking speeds. It is also noted that the highest peak of EMG activity was located just before heel strike. In stance phase, the EMG activity starts to decrease only after 100ms from heel strike as shown in Figure 5.1. The EMG activity drops to the lowest levels after 200ms from heel strike. The normalised EMG signal of volunteer 1 is similar to the one shown in figure 4 in [102]. However, the other volunteers showed patterns relatively different from the first. For instance, the inactivity period after heel rise is not clear in volunteers 2, 3, and

4 at the three walking speeds. It is also noticeable that the tibialis anterior with volunteer 3 is active most of the gait cycle as shown in Figure 5.2.

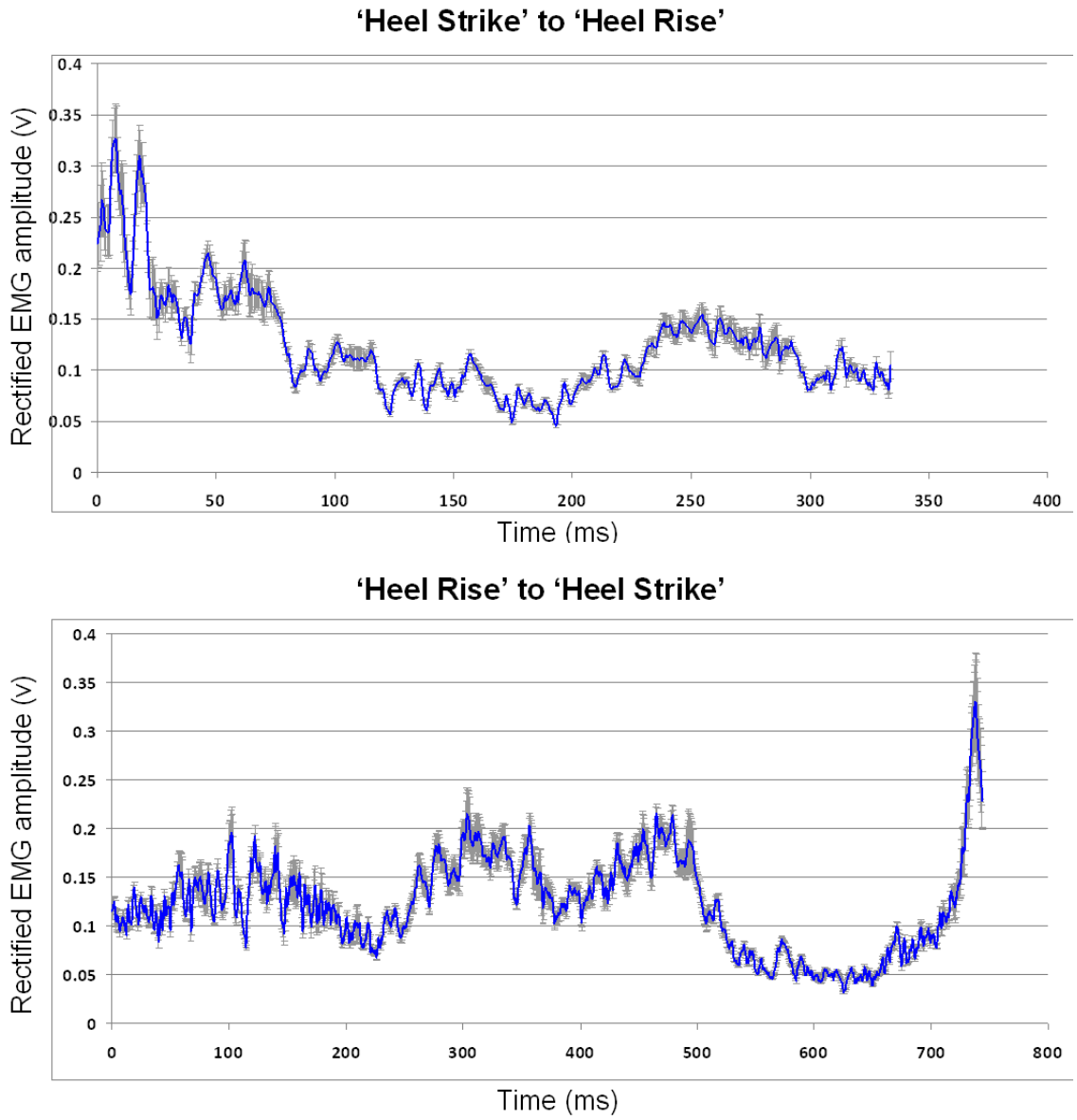


Figure 5.2: Rectified EMG signal of the tibialis anterior during a gait cycle (volunteer 3 – normal walking speed)

Moreover, it is noticed that speed has an effect on the EMG activity patterns for all volunteers in terms of amplitude and activation periods. This was also found by Byrne et al [103] and Hortobágyi et al [104].

5.2.2 Effect of delayed stimulation on drop foot users

Three volunteers were recruited for this experiment. They were given a unique reference code for personal data protection (DS02, DS03, and DS04). All three

volunteers are current drop foot stimulator users. One of the volunteers was wearing a Silicon Ankle Foot Orthosis (SAFO) which is used to help stabilise the ankle and restricts the movement in the ankle joint. Therefore, ankle dorsiflexion data recorded with this patient is likely to have been affected by the SAFO, so the data from this volunteer was not processed. However, the feedback from the patient and the clinician was included in the results discussion as qualitative data, with details being given in Appendix I.

The feedback from clinicians suggests that delays up to 75ms did not show significant effect on the response to stimulation with the three patients. The effect of delayed stimulation started to be noticed by the clinicians at 100ms with patients SD03 and SD04. Yet, the response was still acceptable up to 150ms with the three patients according to the clinicians' feedback. Delays more than 150ms started to have a visual effect on the gait pattern resulting in more inversion and hip hitching. Hip hitching is common with drop foot patients, when trying to compensate for the inability of dorsiflexion by leaning on the side and lifting the leg to raise the foot.

Patients' feedback was similar to the clinicians', as the scoring started to decrease only from delays equal to or greater than 100ms. The scoring system is explained in Chapter 4 and in Appendix I. Patient DS02 scored the trial with 200ms delay better than the ones with 150ms and 100ms. Patient SD03 scored the trial with 100ms the best from all the trials. This shows the subjectivity of the feedback which is based on multiple factors including sensation, fatigue …etc. However, both clinicians and patients expressed the opinion that delays of up to 100ms were acceptable.

Data collected from the optical motion capture system in the Gait Laboratory was used to estimate the dorsiflexion/plantarflexion angles during one step for each introduced delay. This data was used to produce the graphs during the swing period only, which are presented in Figure 5.3 and Figure 5.4. Swing was chosen because it is the period when the foot needs to be cleared from the floor, i.e. stimulation comes in effect. The swing phase here is defined from toe off to heel contact.

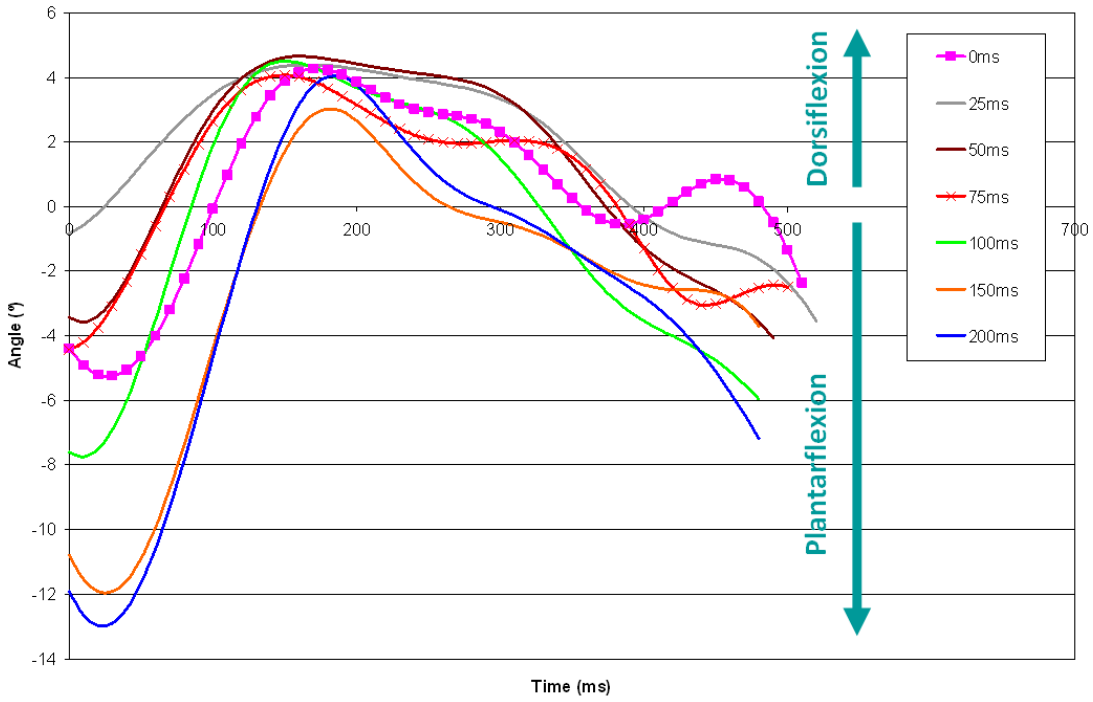


Figure 5.3: Dorsiflexion/Plantarflexion angles during swing for each introduced delay recorded with Patient DS03

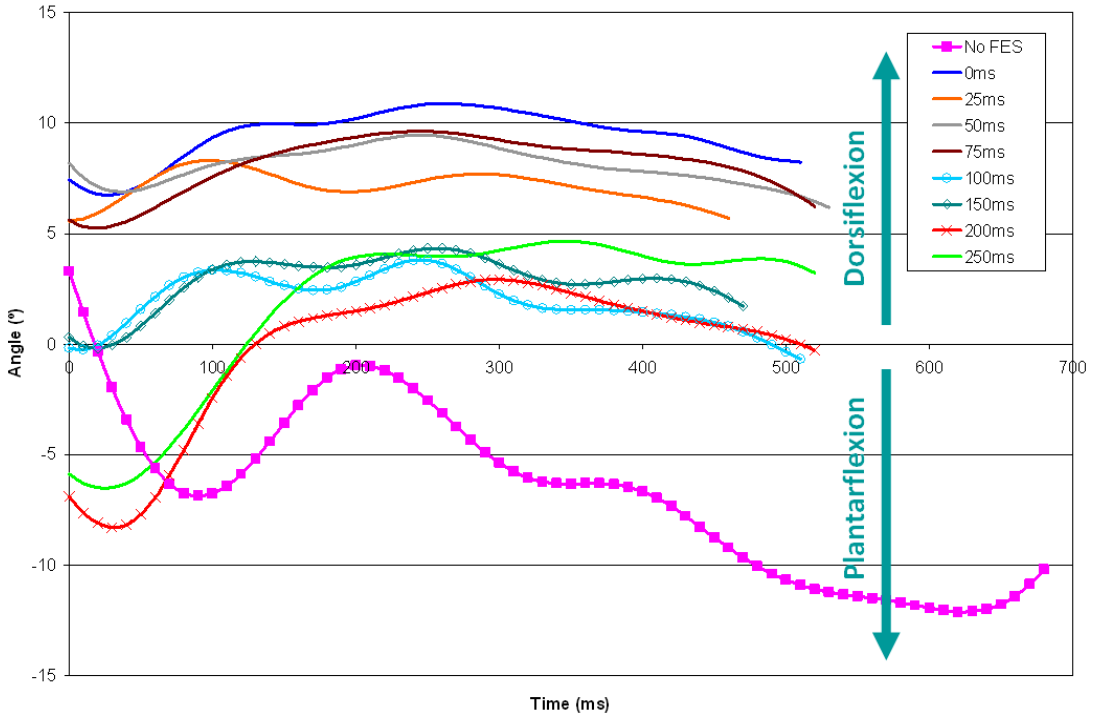


Figure 5.4: Dorsiflexion/Plantarflexion angles during swing for each introduced delay recorded with Patient DS04

All the graphs start from the time the toe is off and stop at the first contact of the foot with the floor (heel strike). Depending on the walking speed, the length of the swing phase varies from one trial to the other and from one person to the other.

Graphs of patient DS03, Figure 5.3, show similar patterns of ankle movement in all trials. The foot starts plantarflexed and gradually dorsiflexes to achieve the maximum angle mid-swing. Then, the dorsiflexion decreases until the initial contact. The main difference between these graphs is the value of plantarflexion they start off with and the angle of the ankle prior initial contact. It is clear from the graphs that the trials with 150ms and 200ms delay start with the largest plantarflexion (-11º and -12º). The trials with 0ms, 50ms and 75ms all start from similar values (around -4º). The trial with 100ms delay starts with a plantarflexion of -7.8º and reaches similar values of trials '0ms', '50ms' and '75ms' within one degree after 100ms. Similarly with the trial '25ms' which starts at an angle of -0.8º and then it follows the three trials within one degree. The largest plantarflexion prior to initial contact was in the trials '200ms' and '100ms'. In addition, all the trials had plantarflexion angles between -2º and -7º prior to heel strike.

Patient DS04 had more distinct graphs. The graphs can be grouped in three patterns. The first one includes trials with delays below 100ms (0, 25, 50, and 75ms). The foot in these trials is dorsiflexed by angles between 5º and 12º during all the swing phase. The second pattern includes trials '100ms' and '150ms' which show that the foot is also dorsiflexed during all the swing phase yet with smaller angles (0º to 5º). The third pattern appears for trials with delays above 150ms (200ms and 250ms). In these last two trials, the foot starts the swing phase plantarflexed by -6º and -7º. After 150ms from the start, these two graphs approach the ones from the trials '100ms' and '150ms'. Figure 5.4 also includes a trial in which the patient was asked to walk without stimulation. This trial shows how the foot is plantarflexed most of the swing phase. This is the consequence of drop foot which is the inability to dorsiflex the foot.

5.3 Wireless testing

5.3.1 Reliability and latency experiments

5.3.1.1 Reliability and latency experiments - Bench tests

The experiments in the laboratory were set to run for just over 10,000 transmissions. The transmission rate was one transmission every 428ms (equivalent to a gate rate of 1.17Hz including two transmissions per gait).

5.3.1.1.1 Interference free evaluation

The recorded data was processed and used to calculate the latency of each transmission during the trial in addition to estimating the reliability. Latency values were plotted on a graph shown in Figure 5.5 as well as the distribution of these values. Table 5.1 summarises the results of the experiment.

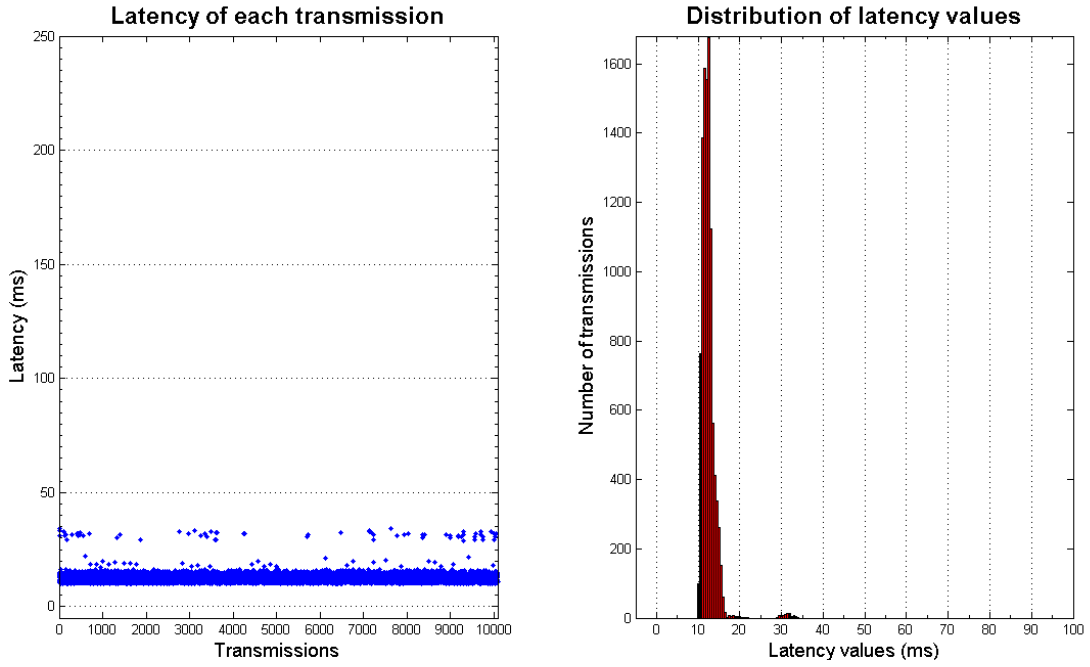


Figure 5.5: Latency representation of the interference free experiment

Number of transmissions	Transmission reliability	Missed events	Median latency (ms)	Average latency (ms)	Maximum Latency (ms)	Latency within 100ms
10091	100%	0	12	12.411	34	100%

Table 5.1: Interference free experiment results summary

All transmissions were received successfully within 34ms. It is also noticeable that there are two bands of latency values; the first one between 10 and 22ms which includes most transmissions (99.32%). The second one ranges from 29 to 34ms and represents 0.68% (69 values) of all transmissions.

5.3.1.1.2 Evaluation with Wi-Fi interference

Summary of results from the 12 trials are given in table 5.2. The table gives details on reliability and latency including: median and average values of latency, the maximum value of latency within the trial, and a percentage of transmissions received successfully within 100ms from all the transmissions. Figure 5.6 represents two graphs of the latency data of trial 12 which shows the lowest performance in terms of reliability and latency. Graphs of the other trials are given in Appendix G.

Trial	Number of transmissions	Transmission reliability	Missed events	Median latency (ms)	Average latency (ms)	Maximum Latency (ms)	Latency within 100ms
1	10373	100%	0	12.5	17.393	92.5	100%
2	10347	99.88%	12	14.5	20.248	167	99.87%
3	10353	100%	0	12	17.98	90	100%
4	10597	99.83%	18	12.5	14.17	227.5	99.77%
5	10524	100%	0	13	15.825	109.5	99.99%
6	10605	100%	0	12.5	13.756	214.5	99.99%
7	10647	99.96%	4	13	15.792	236.5	99.90%
8	11297	99.77%	26	12.5	14.666	97	99.77%
9	10499	100%	0	13	15.676	127.5	99.96%
10	10609	100%	0	12.5	13.117	76.5	100%
11	10537	100%	0	12.5	14.057	98.5	100%
12	10517	99.66%	36	13.5	18.355	250.5	99.32%

Table 5.2: Summary of results from the Wi-Fi experiment

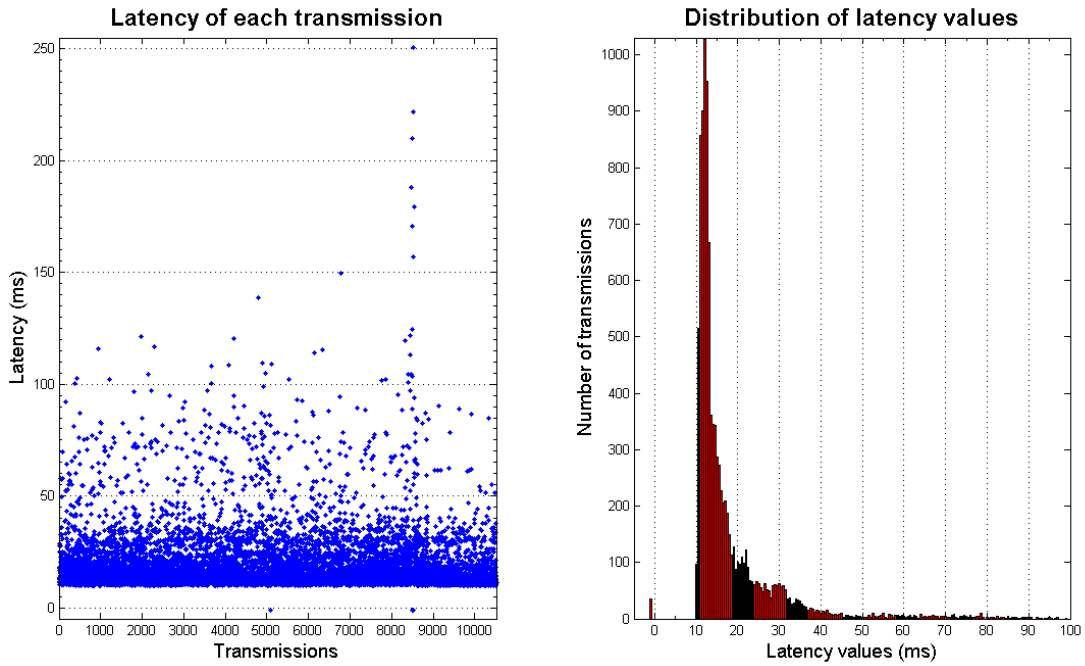


Figure 5.6: Latency representation for trial 12 (WiFi interference)

The graph representing data from trial 12 shows higher latency values compared to the ones from the interference free experiment and the other 11 trials. It is also noticeable that the two bands have disappeared from this graph. However, they are still visible in trials 1, 2, and 3 (see Appendix G, section G.1). The lowest performance of this trial was between transmission number 8480 and transmission number 8550, where 34 events were missed and six latency values were above 150ms. All latency values in the rest of the trial were below 150ms. This is caused by a temporary increased transmission rate at the Wi-Fi router. This can be seen in the spectral view in Figure 5.7 which represents a waterfall graph of spectral activity over time for each ZigBee channel (frequency).

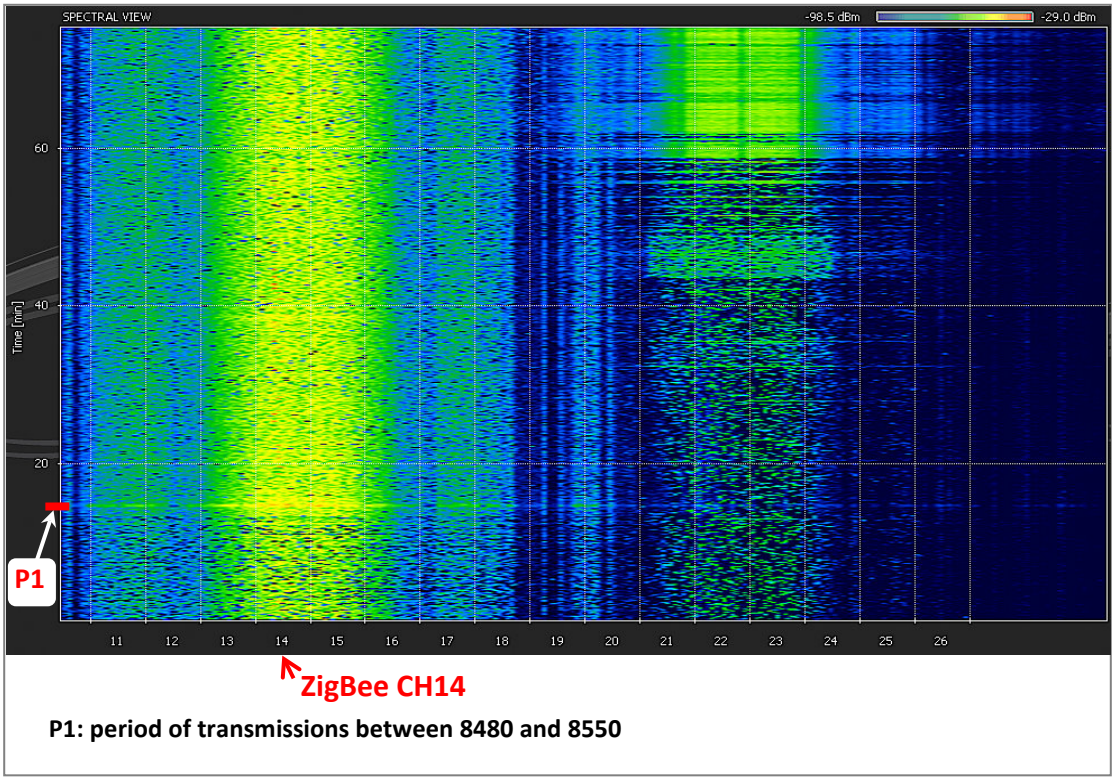


Figure 5.7: Waterfall graph of spectral activity during trial 12 (Wi-Fi interference)

5.3.1.1.3 Evaluation with Bluetooth interference

Results of reliability and latency of the three trials are summarised in table 5.3. Figure 5.8 represents the latency data from trial 1 which had the lowest reliability. Graphs of the other trials are given in the Appendix G. It is noticeable from the graph of distribution of latency values that two distinct peaks separated by about 20ms appear in this trial which are similar to the two bands seen in the interference free experiment. This, however, is not seen in the other trials from the same experiment.

Trial	Number of transmissions	Transmission reliability	Missed events	Median latency (ms)	Average latency (ms)	Maximum Latency (ms)	Latency within 100ms
1	10587	99.91%	10	13.5	19.516	247.5	99.78%
2	10717	99.96%	4	12	12.424	56.5	99.96%
3	10877	100%	0	12	12.518	59.5	100%

Table 5.3: Summary of results from the Bluetooth interference experiment

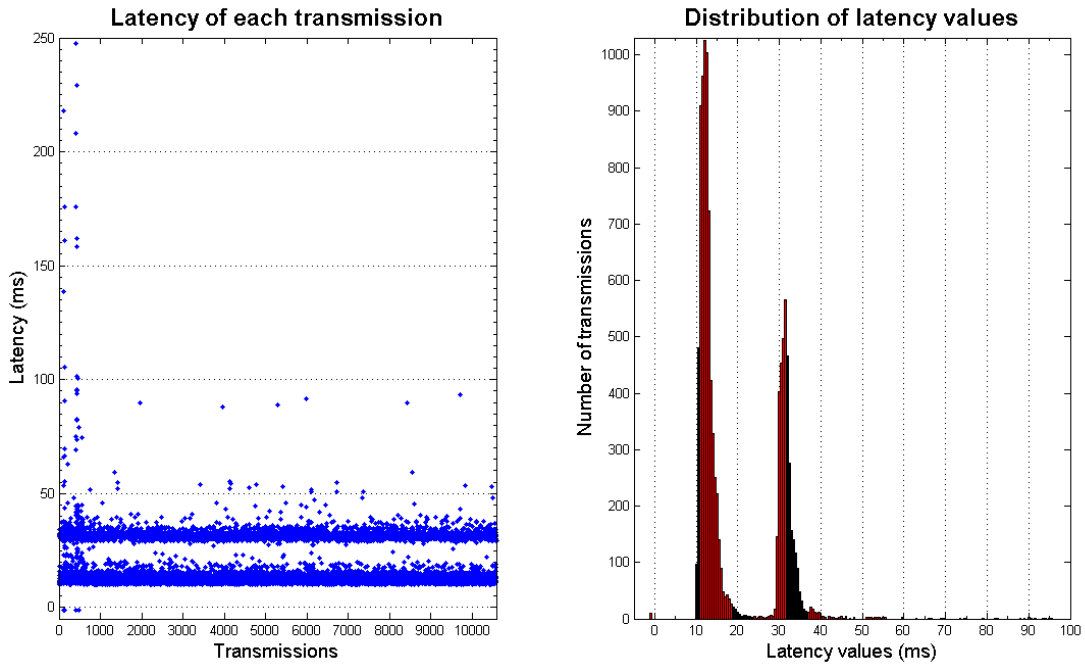


Figure 5.8: Latency representation for trial 1 (Bluetooth interference)

5.3.1.1.4 Evaluation with ZigBee interference

The summary of results of this experiment is given in table 5.3. Latency results from trial 3 are given in Figure 5.9. The remaining graphs are given in Appendix G.

Trial	Number of transmissions	Transmission reliability	Missed events	Median latency (ms)	Average latency (ms)	Maximum Latency (ms)	Latency within 100ms
1	10591	100%	0	12	12.401	63	100%
2	10638	100%	0	12	12.429	56	100%
3	10619	99.98%	2	12	12.443	71.5	99.98%
4	10625	100%	0	12	12.445	54	100%

Table 5.4: Summary of results from the ZigBee interference experiment

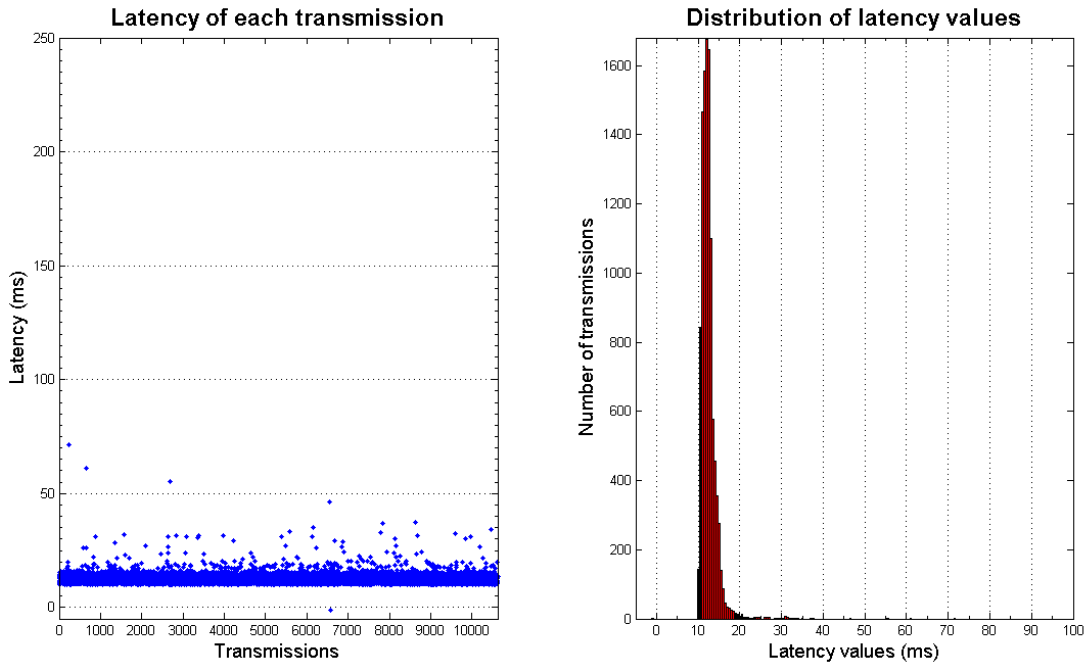


Figure 5.9: Latency representation for trial 3 (ZigBee interference)

5.3.1.1.5 Evaluation with microwave oven interference:

Results of the two trials are summarised in table 5.5 and graphs from trial 2 are given in Figure 5.10. Graphs of trial 1 are given in the Appendix G.

Trial	Number of transmissions	Transmission reliability	Missed events	Median latency (ms)	Average latency (ms)	Maximum Latency (ms)	Latency within 100ms
1	779	100%	0	13.5	18.291	80.5	100%
2	781	99.74%	2	15.5	20.789	88	99.74%

Table 5.5: Summary of results from the Microwave oven interference experiment

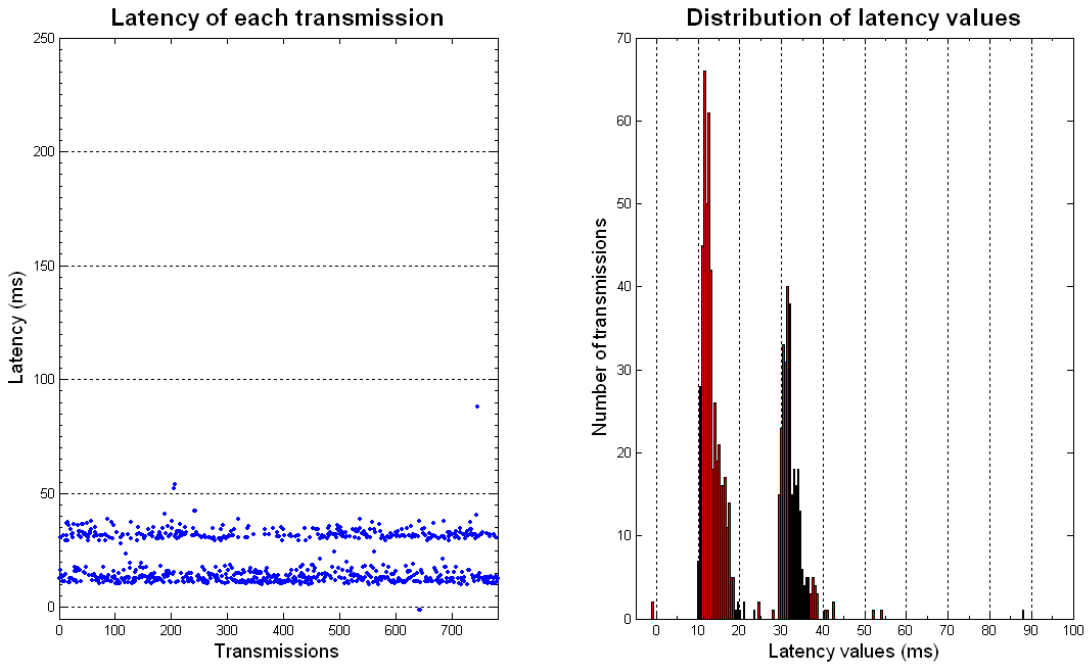


Figure 5.10: Latency representation for trial 2 (Microwave oven interference)

5.3.1.1.6 Effects of loaded stimulation output:

This experiment tested the effect of the stimulation output stage on the behaviour of the wireless system. The summary of latency and reliability results are given in table 5.6 and represented in Figure 5.11.

Number of transmissions	Transmission reliability	Missed events	Median latency (ms)	Average latency (ms)	Maximum Latency (ms)	Latency within 100ms
11567	100%	0	12	12.26	31	100%

Table 5.6: Summary of results from the experiment with stimulation load

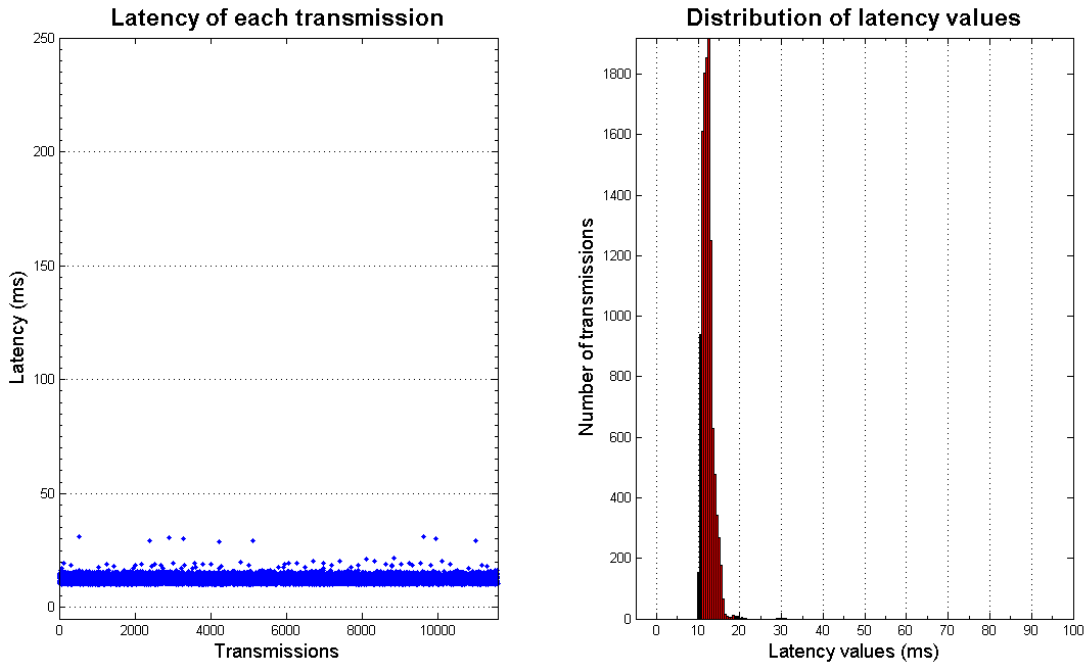


Figure 5.11: Latency representation (loaded stimulation experiment)

5.3.1.2 Reliability and latency experiments - Real world condition experiment

Six healthy volunteers where recruited for this experiment. Each trial was conducted at different time of the day but all during the working hours. This ensures that the Wi-Fi networks and cordless phones are being used, therefore causing interference to the wireless FES system. The summary of latency and reliability of all trials is given in Table 5.7.

Volunteer	Number of transmissions	Transmission reliability	Missed events	Median latency (ms)	Average latency (ms)	Maximum Latency (ms)	Latency within 100ms
1	1686	100%	0	12	12.833	127.5	99.94%
2	1867	100%	0	12	12.778	34	100%
3	1842	100%	0	12	12.447	77.5	100%
4	2156	100%	0	12	12.58	74.5	100%
5	1808	100%	0	12	12.299	54	100%
6	1851	100%	0	12	12.688	72.5	100%

Table 5.7: Summary of results from the real world conditions experiments

Figure 5.12 represents latency data from volunteer 1 who had the lowest performance. This trial had only one transmission latency above 100ms. All other trials were similar

with 100% reliability and latency values less than 100ms. Graphs from the other volunteers' are given in Appendix H.

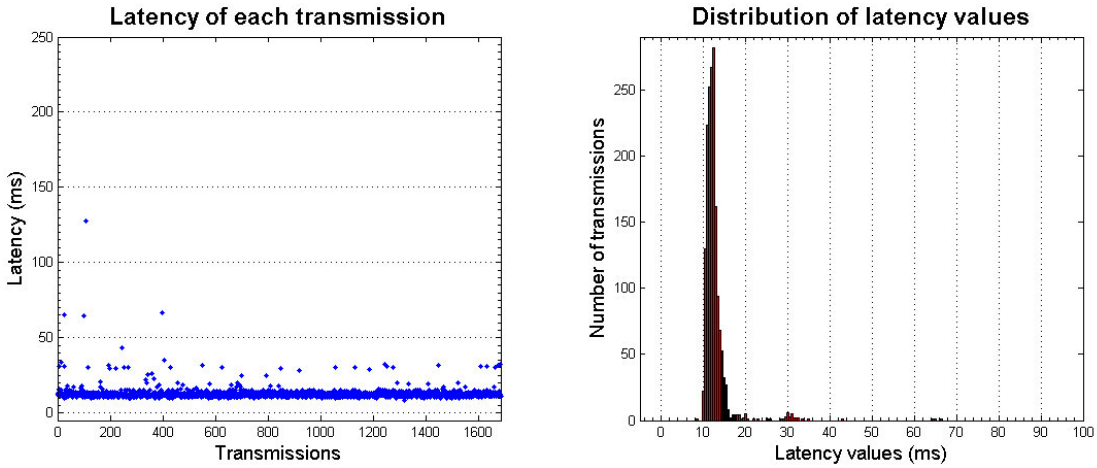


Figure 5.12: Latency representation (Volunteer 1 – real world conditions experiment)

5.3.2 Power consumption experiments

The two experiments were performed in the laboratory at room temperature. The following represents results of these experiments.

5.3.2.1 Wireless footswitch battery test

The footswitch was powered with a fresh battery and left running until the battery failed. The experiment was stopped after eight days, 15 hours and 37 minutes. The number of transmissions read on the EEPROM was 831,331 transmissions which is equivalent to 415,665 steps. The discharge graph of the battery during this experiment is given in Figure 5.13. It is clear that the battery discharges at a slow rate from 3v (when new) to 2.5v. The discharge becomes rapid after this voltage and drops to below 1v in less than four hours and 30 minutes.

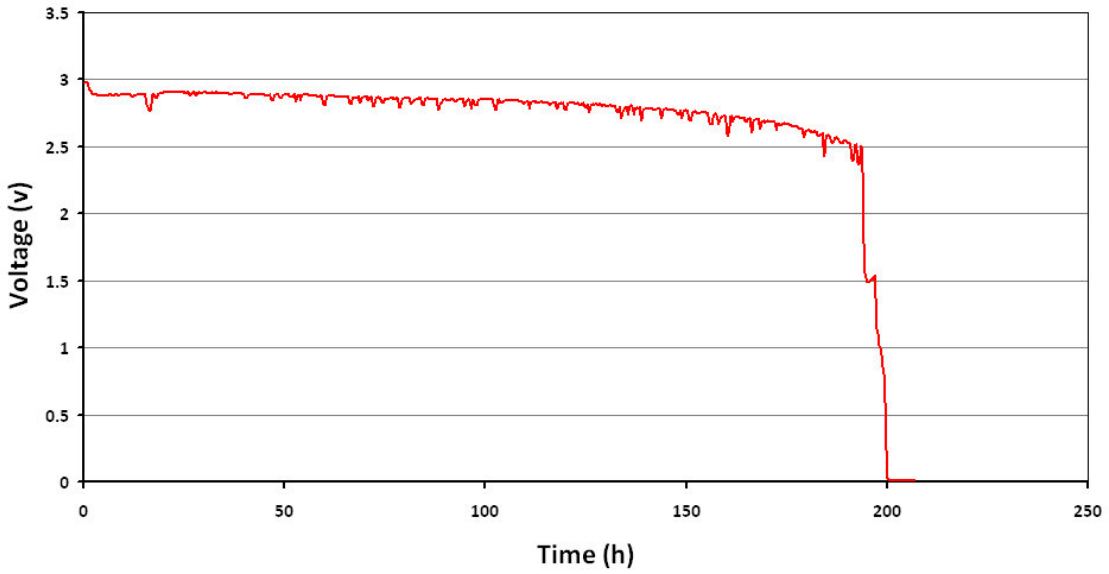


Figure 5.13: Wireless footswitch battery discharge graph

Participants of the wireless footswitch trial have reported that the footswitch battery lasted for three weeks of daily use.

5.3.2.2 Wireless stimulator battery test

As explained in the previous chapter, the wireless stimulator was powered using a fresh alkaline battery (9v PP3 PROCELL Professional, Duracell). The test was stopped after 12 hours and 20 minutes. The total number of transmissions was counted on this node was 22,925 which took place in about 11 hours. This is equivalent to 11,462 steps and therefore over one day's worth of battery life.

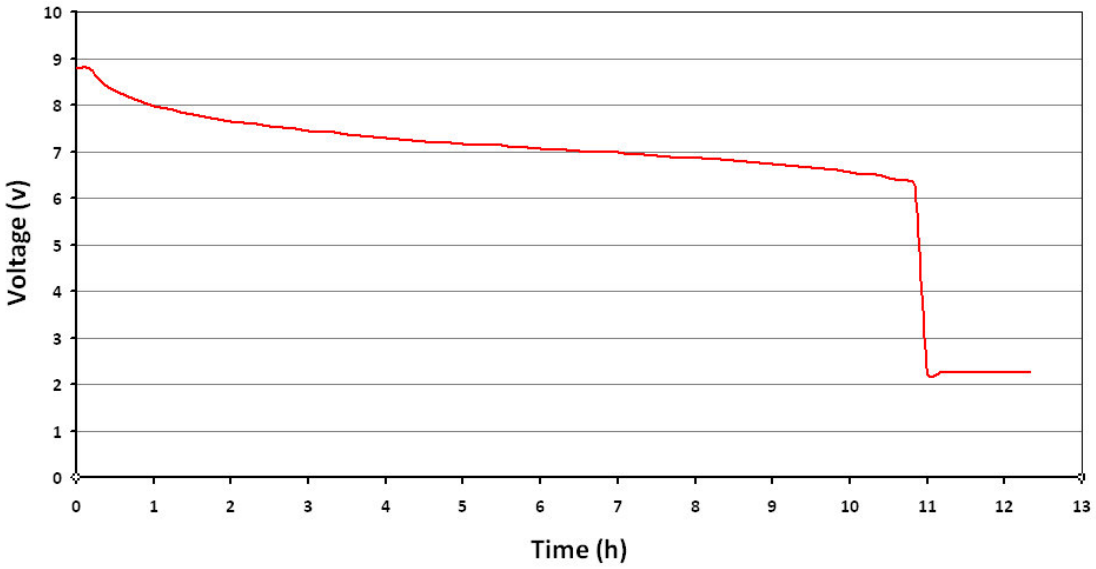


Figure 5.14: Wireless stimulator battery discharge graph

Figure 5.14 represents the battery discharge graph during this experiment. The battery discharged at a relatively slow rate for ten hours and 50 minutes whereupon it reached 6.3v. This was followed by a sharp drop to reach 2.2v in less than 15 minutes.

Initial results of the wireless footswitch patient trials suggest that the battery of the wireless stimulator lasted for about one and half days of use.

5.4 Wireless three- channel stimulator testing

5.4.1 Healthy volunteers experiment

Eleven volunteers took part in the experimental evaluation of the multi-channel FES system. The experimental procedure was explained to all volunteers at the beginning of each trial. Matlab was used to plot the recorded signals and to generate predicted stimulation triggering signals. The predicted stimulation triggers were compared to the recorded ones in order to estimate the reliability and repeatability of the system. Table 5.8 summarises the results of the three channels for each volunteer.

Volunteers	Channel 1			Channel 2			Channel 3		
	No. predicted events	No. False Negatives	No. False Positives	No. predicted events	No. False Negatives	No. False Positives	No. predicted events	No. False Negatives	No. False Positives
1	39	0	0	47	0	0	8	0	0
2	41	0	0	61	1	1	20	0	0
3	37	0	0	45	0	5	8	0	0
4	48	0	0	80	1	1	32	0	0
5	44	0	0	56	3	1	12	2	0
6	38	0	0	54	0	0	16	0	0
7	38	0	0	50	0	0	12	0	0
8	40	0	0	50	0	0	10	0	0
9	42	0	0	50	0	0	8	0	0
10	39	0	0	48	1	1	10	0	0
11	40	0	0	48	0	0	8	0	0

Table 5.8: Statistics of stimulation events of the three stimulation outputs for the eleven volunteers (Three-channel experiment with healthy volunteers).

It is notable that the number of events in channel 1 was approximately the same for all volunteers. However, the number of events in both channel 2 and channel 3 was higher for volunteers 2 and 4 than for the other participants.

Seven of the volunteers showed no false events when compared to the predicted signals. Of the remaining volunteers, only one had more than one false negative. Volunteers 2, 4, 5 and 10 all experienced one false negative followed by one false positive in channel 2. This always occurred under the same condition, i.e. when the system switched from walking mode to standing/sitting mode while the threshold for reaching was achieved. As shown in Figure 5.15, both signals set high and return to the low logic level with a longer delay and longer period in the recorded signal. Due to the structure of the algorithm, used to detect and count the number of false events, it counts one false positive and one negative. This is due to the fact that the algorithm is designed to count the number of events in the recorded signal between two consecutive events in the predicted signal. For instance, in the example shown in Figure 5.15, between rising edge (event 1) and falling edge (event 2) of the predicted signal, there are no events in the recorded signal. So, the algorithm counts one missing event (event 1 missing). Following this, in the period between falling edge and rising edge in the predicted signal, there are two events in the recorded signal (rising edge and falling edge) which results in one correct event (the falling edge) and one extra event. The overall count from this is one false negative and one false positive. This condition results from the fact that there are no latencies affecting the predicted signals while in the recorded signals there are latencies resulting from the wireless system and processing time. Therefore, the system did not actually fail to generate the correct output but due to latencies, in real conditions, the change in the recorded signal was not as fast as the predicted one. As a result, these events were not considered as failed in this thesis.

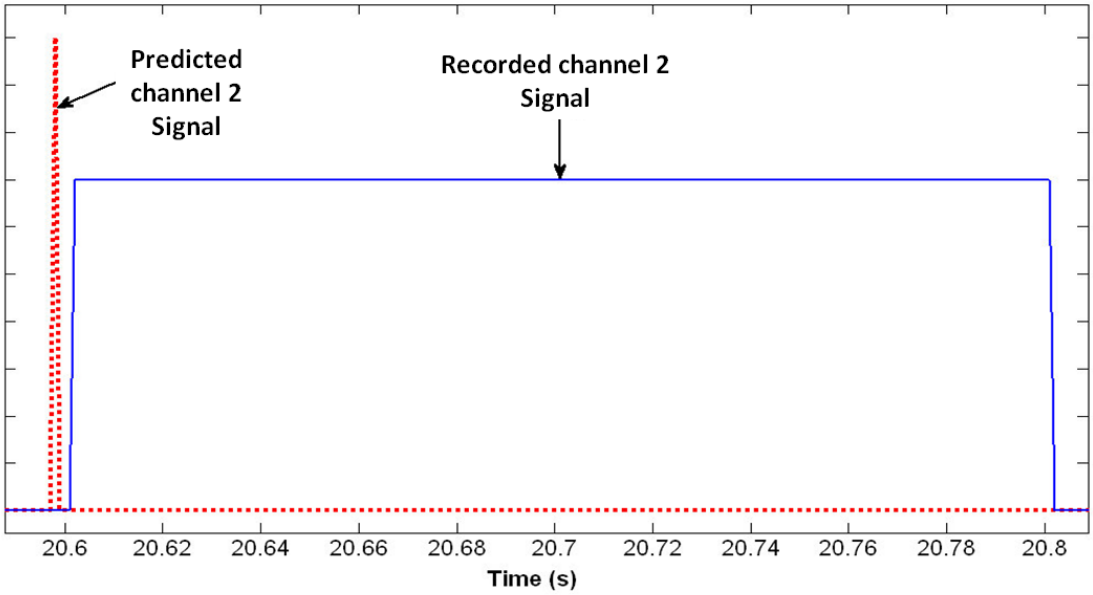


Figure 5.15: Example of the condition causing the Matlab algorithm (used to count false events) to count one false negative followed by a false positive.

Data from volunteer 5 showed that four false negative events were detected, two of which occurred in channel 2 and the other two in channel 3. Both events were predicted to occur during standing/sitting mode and in both channels at the same time. The period of time between the two events in each channel was predicted to be 158ms.

The table shows also that the system generated 5 false positive events for volunteer 3. The first one occurred 161ms after the start of data recording. This may therefore be due to data being clipped between two events when starting recording. The remaining four false positives occurred during the standing/sitting mode while reaching threshold was passed as seen in Figure 5.16. These events would stop and then start stimulation of channel 2. The time between the first two false positives was 200ms and was exactly equal to the time between the two others.

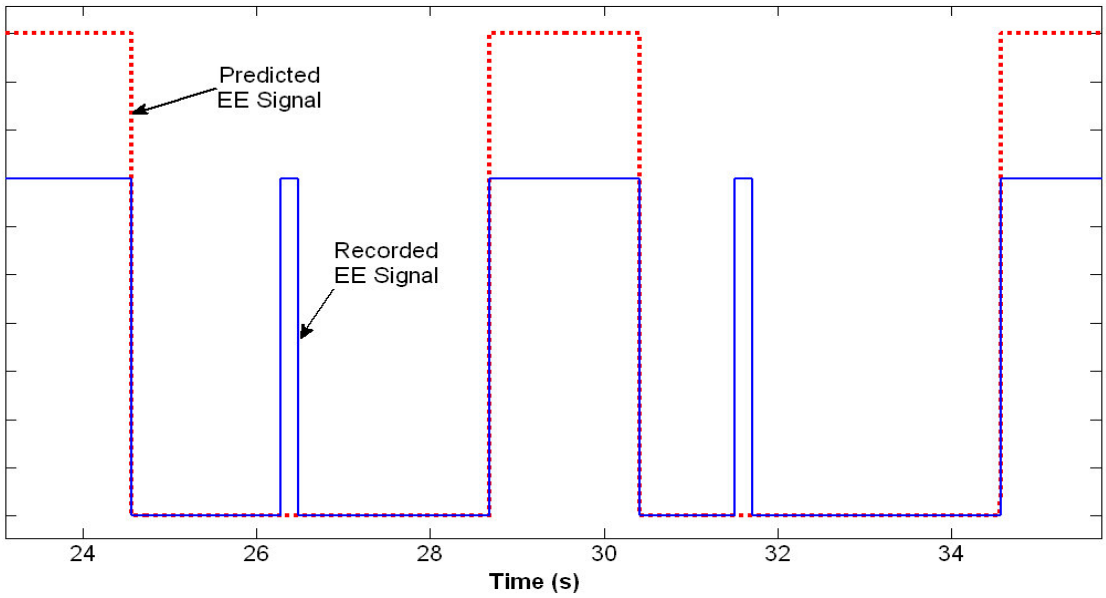


Figure 5.16: Caption of the channel 2 signal (volunteer 3) showing four false positive events generated by the system.

The experiment was repeated 30 times with one of the volunteers. Table 5.9 summarises the total numbers of predicted false negatives and false positives events of the three channels. It shows that only channels 2 and 3 had false negatives and one false positive was detected in channel 2. These false events detected by the algorithm were in the first trial out of 30. After examining the graphs of the two channels, they looked the same as was experienced with volunteer 5.

Channel 1			Channel 2			Channel 3		
No. predicted events	No. False Negatives	No. False Positives	No. predicted events	No. False Negatives	No. False Positives	No. predicted events	No. False Negatives	No. False Positives
616	0	0	585	3	1	134	2	0

Table 5.9: Summary of the number of predicted events, false positives, and false negatives for the three channels recorded with one volunteer and repeated 30 times (three-channel experiment).

Figure 5.17 shows detection of heel events while the volunteer transfers weight without triggering stimulation. This is a result of the walking detection functionality in the wireless footswitch, designed to prevent unwanted stimulation when standing still.

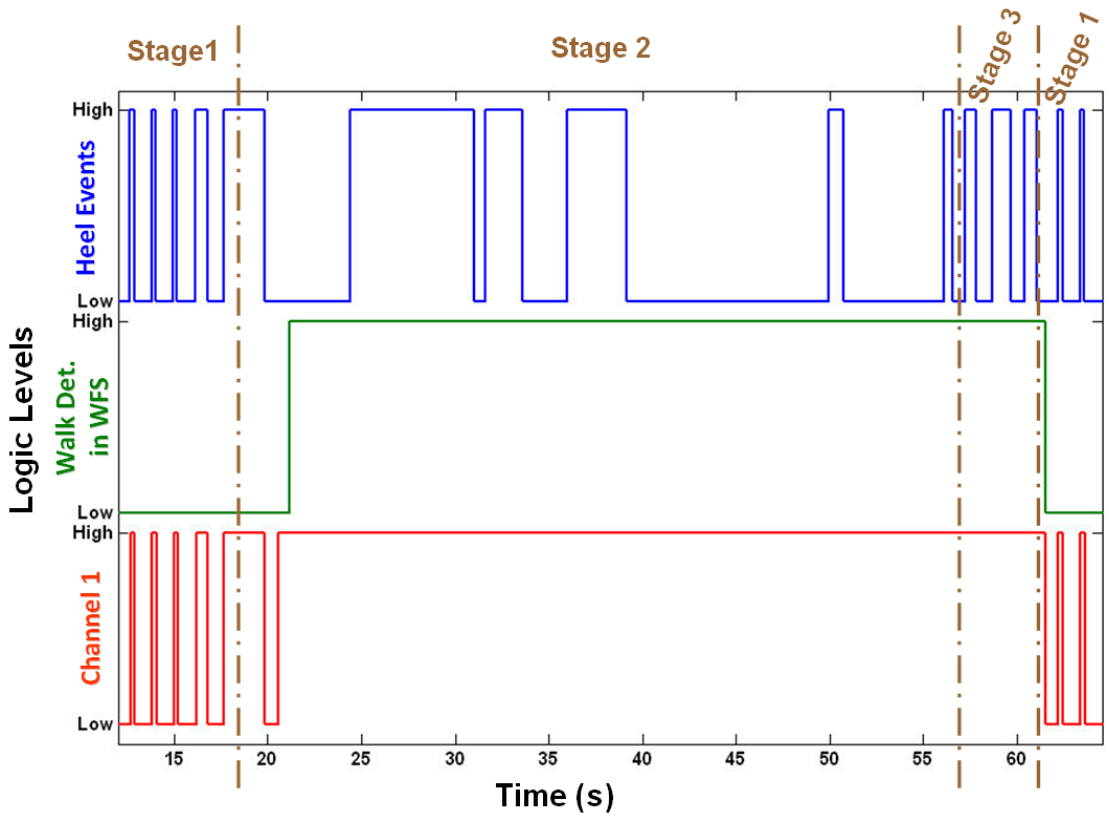


Figure 5.17: Logic levels of heel events signal, walk detection in WFS signal, and channel 1 stimulation trigger signal during three stages of the three-channel experiment (volunteer 2)

Stage 1, in Figure 5.17, represents the walking stage in which it is noticeable that channel 1 stimulation trigger follows the heel event signal in the Wireless FootSwitch (WFS) whilst walk detection signal in the WFS is low. Stage 2 is when the volunteer stopped walking and started reaching. The walk detection signal in the WFS does not set high immediately due to the waiting period of 3s, preset to ensure that the user stopped walking and not to confuse it with slow walking patterns. It is interesting that this volunteer recorded heel events during this stage. This occurred while they were attempting to reach. The system did not stimulate during these events. During stage 3 the volunteer was asked to deliberately transfer weight from one leg to the other to test the effectiveness of this concept. Transition from stage 3 to stage 1 was delayed by 470ms in this particular example. This varies depending on how fast the user starts walking which reflects in how fast the acceleration reaches the threshold for switching to walking mode.

5.4.2 Case study experiment

One patient participated in this case study. The participant was a 50 years old male with a drop foot on the left leg and impairment of the left arm caused by a stroke. This patient has been using drop foot stimulation since February 2009, and participated in a clinical trial on the upper limb (Reach trial [28,32]) which involved exercises of reaching objects without stimulation. The participant can walk without stimulation and the measured average walking speed without stimulation is 0.83m/s. His average walking speed increased to 0.93m/s with drop foot stimulation.

A clinician from the National Clinical FES Centre was present during the experiment and set stimulation parameters for the three stimulation channels. The patient had a good dorsiflexion movement response to stimulation on channel 1 and acceptable hand and arm movement on the other two channels.

The stimulation output of the three channels is represented in Figure 5.18. The stages represented on the figure were defined using the recorded video. During stages 1, 3, and 5 the system successfully generated stimulation in channel 1 and channel 2 except the first step in stage 3, in which only channel 1 stimulated. Although the participant was a fast walker, the two stimulation channels gave him foot clearance and assisted reciprocal arm swing. When the volunteer stopped walking to reach for an object on the table (start of stage 2), he attempted to reach as soon as he stopped. This caused a delay, as seen on the graph, before starting the stimulation because of the preset period of 3s before switching from walking mode to standing/sitting mode. However, after that period, the stimulation worked as expected on both channel 2 and channel 3. Stage 4 was not long enough (less than 3s) to switch from walking mode to standing/sitting mode, since the patient was a fast walker and did not wait for the 3s period. So, although the patient attempted to reach, in order to release the object, this stimulation was not enabled and therefore as seen on the graph no stimulation was applied on channel 2 and 3. The patient successfully dropped the object on the table without help by stimulation and started walking (stage 5).

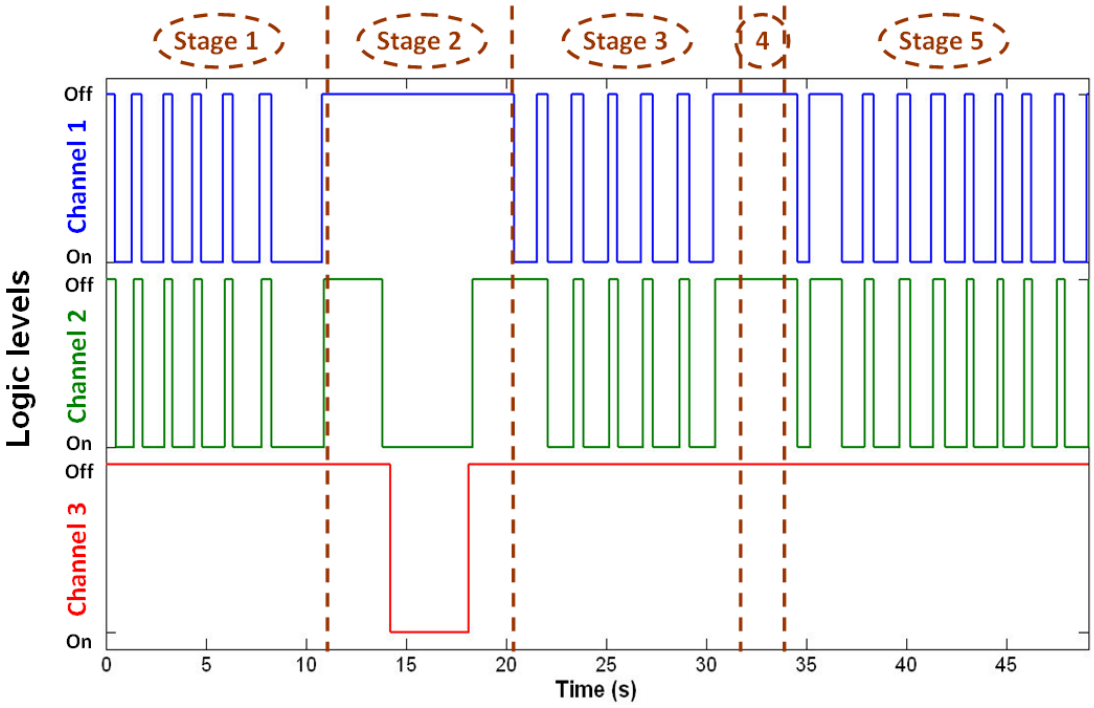


Figure 5.18: Stimulation output of the three channels during one session of the case study

The system also successfully prevented false positive stimulation when the patient transferred weight from one leg to the other. The patient was not asked to perform weight transfer as part of the experiment and the weight changes that did occur did so naturally. This is seen in Figure 5.19, which includes: heel event detection signal on the WFS (heel rise when falling edge, and heel strike when rising edge), walk mode detection signal on the WFS (walk mode when low), and channel 1 stimulation output signal. Stage 2 shows clearly how the system did not generate unnecessary stimulation although the FSR experienced changes of pressure. It is also noticeable that the WFS detected stationary mode less than 3s after the start of stage 2. This happened, as seen on the video, after that the patient stopped walking for about 2s followed by a short movement of the foot forward (heel events seen in the beginning of stage 2). This movement was not fast enough to result in an acceleration value more than the threshold.

Detection of walking at the start of stage 5 was delayed, which resulted in a delayed stimulation in channel 1. This might be due to a slow start in walking which did not cause the acceleration to reach the predetermined threshold soon enough to activate channel 1 stimulation.

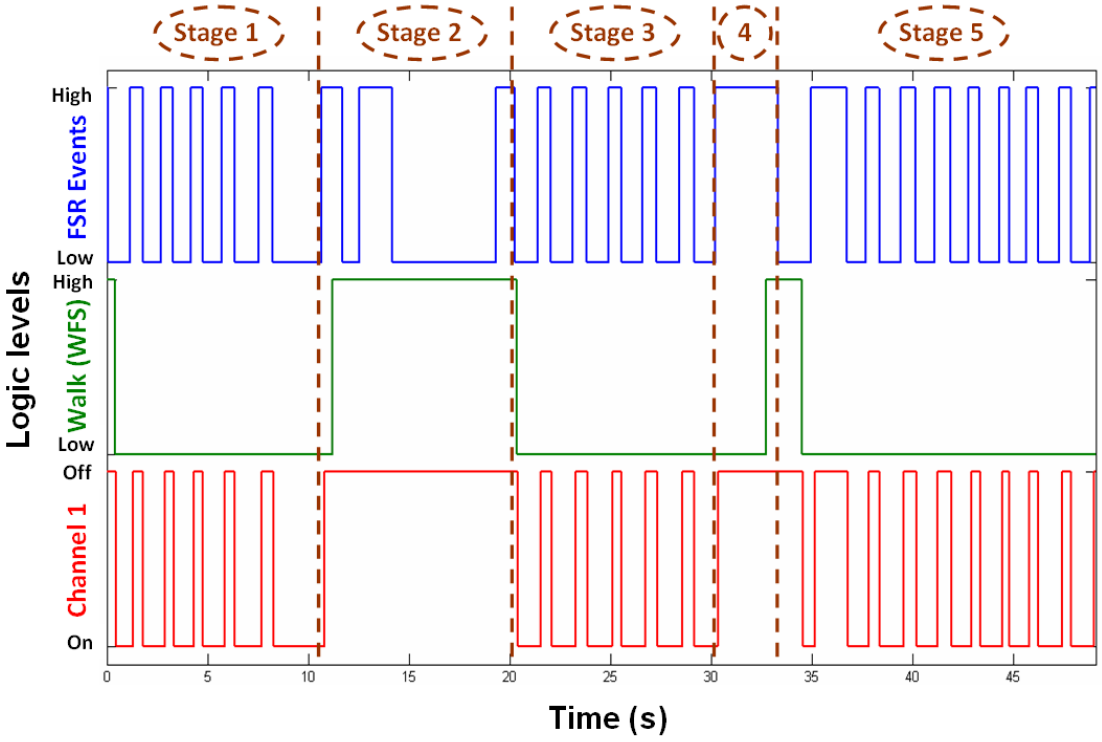


Figure 5.19: Logic levels of heel events as detected using the FSR only, walk detection in WFS signal, and channel 1 stimulation trigger signal during the case study of the three-channel system

During the second trial, which involved reaching for an object placed on a table whilst sitting, triggering of stimulation was not effective for all attempts. However, after changing the threshold settings of the accelerometer on channel 2, the stimulation triggered successfully in the channels used for reaching. The threshold values were increased which results in a higher triggering angle than the initial setting.

After analysing the video and further investigation, it was found that while sitting the arm rests at an angle and not in the neutral position (0º shoulder flexion). On the other hand, when the person is standing, the arm does rest at 0º shoulder flexion. For this reason, the initial settings of accelerometer thresholds triggered successfully reaching stimulation. However, when the patient was sitting, the resting position of the arm was over the threshold angle which made it hard to trigger.

5.5 Summary

Experimental results of the dorsiflexion timing experiment were not conclusive due to the variability of EMG signals and the relatively low number of subjects. The results of the delayed stimulation, on the other hand, were correlated between subjects and were used to define the maximum acceptable latency.

Results of the in-laboratory experiments of the first prototype showed that the lowest reliability and highest latencies were caused by Wi-Fi when placed close to the proposed wireless system. The battery experiments were encouraging as the results showed that the system exceeded the requirements. The real life experiment with healthy volunteers showed that the wireless single channel FES system worked reliably with low latency.

The experiments on the second prototype showed that the system worked as expected with only few missed events in channel 2 and channel 3. The weight transfer detection in stationary mode worked successfully with both; healthy volunteers and the volunteer recruited for the case study.

Chapter 6 - Discussions of Experimental Results

6.1 Introduction

This chapter presents a discussion of the results obtained from the experiments on both the first and second prototypes. The first part of this chapter discusses the results of the experiments designed to verify the feasibility of a wireless FES system. This includes the experiments on reliability, latency and power consumption. The second part discusses the experimental results of the three-channel FES system proposed in this research project.

6.2 Defining latency specification

6.2.1 Dorsiflexion timing experiment

Variability of EMG signals is expected between one person to another, however, the difference found in this experiment was significant compared to the averaged normalised data found in the literature, except volunteer 1. This is due to the gait pattern of the recruited volunteers. During the experiment, it was noticed that volunteer 2 had a small dorsiflexion angle. Volunteer 2 also reported that he had participated in the past in a similar experiment where they were recording EMG signals from the tibialis anterior and calf muscle. They found that volunteer 2 had double activation of both muscles during gait which could explain the noticeable difference in EMG pattern.

Intensive EMG activity in volunteer 3 is related to the gait pattern which looks as if the foot hits the ground firmly and starts dorsiflexion even before heel rise. Volunteer 4 mentioned that he has flat feet which would have an impact on the gait pattern and therefore it explains the difference found with this volunteer and the others.

These results show that EMG signals can be significantly different between individuals due to the gait pattern. This supports the discussion in Chapter 2 on the problem of using EMG signals to trigger stimulation, since in such a small sample of healthy subjects, the signals are significantly different. Therefore, as people with neurological

disabilities have a greater variability of gait patterns, this difference is likely to be even more significant.

The protocol of recruiting volunteers should include observing their gait by an expert in order to identify subjects with unimpaired gait patterns. Moreover, ideally the number of volunteers should be more than the four used for this experiment.

Due to the time constraints, and as mentioned earlier, due to the fact that this research does not focus on EMG activity of the tibialis anterior, this experiment was not repeated on other volunteers. Instead, the collected data was used to measure average timings of gait phases of the volunteers (from heel rise to heel strike and from heel strike to heel rise). This was used in other experiments to define the gait cycle rate i.e. number of steps per second for an unimpaired subject.

Due to the differences between unimpaired and impaired gates, the activation timings based on healthy subjects only would not suit all patients. Therefore, a more accurate method of defining the maximum acceptable latency needed to be used. The second method that was thought to be more accurate was applying stimulation on drop foot patients with a delay, in order to observe the effect of the introduced delay. This then could be used to define the maximum acceptable latency that does not affect the effectiveness of stimulation.

6.2.2 Effect of delayed stimulation on drop foot users

As described in Chapter 5, qualitative data (feedback from patients and clinicians) correlated with the quantitative data (optical motion capture data) in terms of delays up to 100ms which did not cause a visible effect on the gait of the two patients. The trials starting with a relatively long delay, of more than 100ms, required compensation in the other joints in order to clear the foot from the floor. This explains the clinicians' feedback on trials with delays above 100ms.

Data from patient DS04 suggested that the foot is dorsiflexed during all the swing phase (i.e. foot cleared from the floor) for all the trials with delays up to 150ms. With longer delays, although the foot starts the swing phase plantarflexed, the foot is dorsiflexed after 150ms. Moreover, comparison of all the trials 'with stimulation' with the trial 'No FES', it is clear that the foot is better cleared off the floor even with a stimulation delay of 250ms. These results can not be generalised due to the variability inter-subject and intra-subject. More patients need to be recruited for this experiment in order to estimate

more objectively the effect of delayed stimulation on the gate pattern. However, these results could be used as guidance, since the motion capture data correlates with the feedback given by clinicians and patients. Moreover, the stimulation parameters for drop foot usually include a rising ramp period which consists of a linear increase of stimulation level at every pulse until it reaches the suitable stimulation level. This period is to prevent spasticity and not to cause discomfort, as suggested in the clinician's manual of the ODFS Pace (OML, UK). The rising ramp is set up for each patient individually, and the default value in the ODFS Pace is 200ms. Therefore, although the wireless system introduces latency in the system, the rising ramp value could be changed to compensate for this additional delay. Nevertheless, based on the delayed stimulation experiment, this work will consider delays up to 100ms as acceptable values for an effective stimulation.

6.3 Wireless testing

6.3.1 Reliability and latency experiments

The experiments in the laboratory environment were designed to test the system in most of the expected conditions in terms of interference. These experiments included testing the system with the most likely sources of interference in everyday use and repeated to cover most possibilities. For instance, the Wi-Fi interference experiment was repeated 12 times to ensure that the system is tested under worst case conditions. These results were published in a conference paper [105] (Appendix M).

Overall, these experiments showed encouraging performance. In 'interference free' conditions the system achieved a reliability of 100% and latency values below 35ms for over 10,000 transmissions. The results of this investigation also showed that the system can work continuously for long periods and for a high number of steps.

Wi-Fi was the strongest source of interference to the system in certain arrangements. Placing the router between the two nodes while transferring data at high rate (>100kByte/s) resulted in the lowest reliability (99.66%) of all the experiments. It also resulted in the highest number of transmissions with latencies above 100ms (0.32% of all received transmissions). This brings down the reliability considering only received transmissions within 100ms to 99.32%. This value is still acceptable knowing that this arrangement of nodes and Wi-Fi router is very unlikely to be encountered in every day

life, and if it was, it would not last for long periods, since the user is walking whilst the router is fixed. This is due to the fact that the router was placed only 30cm in-between the two nodes of the system on the same horizontal level. Moreover, as shown in this experiment, the further away the Wi-Fi router is placed, the higher the reliability is and the lower the latency. Therefore, even when the patient is walking next to a Wi-Fi router which is streaming data at a high bit rate, the proximity would not last for more than few seconds, and in these few seconds of proximity the device is over 99.32% reliable. This will be followed by an improvement of performance since, as found in the experiment, the system had a 100% reliability and 99.99% of all transmissions received within less than 100ms in trial 5, which involved locating the Wi-Fi router in the same room and only 20cm from the wireless footswitch (both on the floor and the stimulator node on a desk). Moreover, these experiments were performed at a relatively high transmission rate in the wireless FES system, compared to real conditions. As explained in Chapter 4, the rate was chosen for a fast unimpaired walking gait which is usually slower with patients. This might have lowered the performance of the system since as explained by Shuaib et al. in [106], the bit error rate increases with data rate in ZigBee. Therefore, in real conditions the performance of the system could be better than the ones in the laboratory conditions. In addition, despite the fact that a transmission delayed by more than 100ms can affect the effectiveness of stimulation, it might not affect the safety of the system as found in the delayed stimulation experiment.

This experiment showed that ZigBee can coexist with Wi-Fi even when exposed to high levels of interference from a Wi-Fi router. This can be explained by the fact that ZigBee uses an anti-collision mechanism known as Carrier Sense Multiple Access with Collision Avoidance (CSMA-CA) [85]. This measures the spectral activity of the radio channel used and waits until the channel is quiet to transmit. However, this might result in an increased latency if the duty cycle of the interfering system is large. This was the case with Wi-Fi which can have a high duty cycle when transferring data at a high bit rate. This explains the increased latency noticed in this experiment.

The first few minutes of trial 1 of the Bluetooth interference experiment showed high latency values and 10 missed events (the only missed events recorded during this trial). The performance improved significantly during the rest of the trial and no more failed transmissions were recorded. Considering only the period of the first 500 transmissions in trial 1, the system had relatively low performance which resulted in one failure every

50 transmissions. The effect of these first few minutes of trial 1 could not be repeated even under the same conditions. This shows the unpredictability of these systems since they can be influenced by many variables. However, the system showed that it could improve significantly and coexist with Bluetooth since there was no failure in transmission in the rest of this trial. In addition, more than 99.78% of all transmissions were received successfully within 100ms for the other three trials. The proximity of the Bluetooth source seems to affect the latency and reliability, especially when the Bluetooth source is close to the wireless footswitch, as found in trial 1 in which the distance from the Bluetooth source to the wireless footswitch was 10cm. Therefore, in order to ensure high performance of the wireless FES system, any device streaming data using Bluetooth should be kept more than 10cm from the wireless footswitch. For instance, a phone with Bluetooth enabled should be on the contralateral side from the wireless FES system as an extra precaution.

The spectrum analyser shows that the Bluetooth network was overlapping with the ZigBee channel used during trial 1 (Figure 6.1). Bluetooth is designed to avoid noisy channels and adapts its frequency hopping sequence not to include these channels. As seen in Figure 6.1, Bluetooth is avoiding the overlapping channels with Wi-Fi channel 11. However, due to the small duty cycle of the ZigBee network, Bluetooth does not consider the channel used by ZigBee as noisy. hence the overlapping channels were kept in the hopping sequence which could have resulted in collision if not detected by CSMA-CA [99].

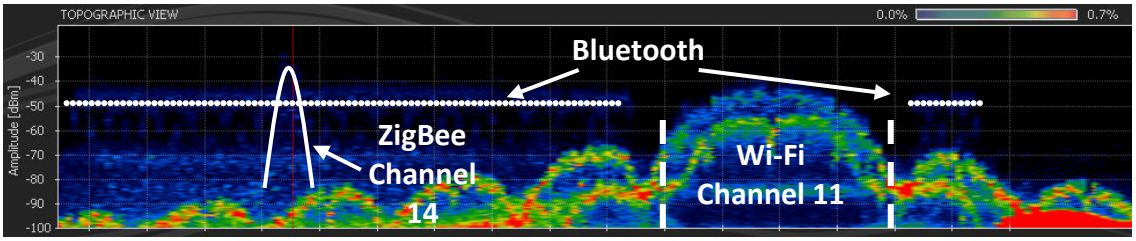


Figure 6.1: Topographic view of the 2.4GHz band (Bluetooth interference experiment, trial 1)

Coexistence with another ZigBee network did not cause a drop in performance in the four arrangements tested. The location of the second network did not seem to affect reliability or latency of the system. This is due to the relatively low duty cycle of ZigBee which means that devices are silent most of the time. This leaves the channel quiet for other networks to use, including ZigBee. Despite the fact that two transmissions failed in trial 3, all trials showed strong reliability and over 99.98% of all

transmissions received within the 100ms latency limit. This shows the low risk of interference when two or more users of the proposed system are within range and using the same ZigBee channel.

The microwave oven used for the fifth experiment did not cause a significant drop in performance of the tested system. The reliability of receiving events successfully within 100ms was over 99.74%. Microwave ovens are designed not to let radiation of electromagnetic waves escape outside. However, depending on the manufacturer and what is placed inside the oven, they can leak some energy [107]. Despite this, microwave ovens have a duty cycle less than 100% so there are quite periods in which ZigBee can transmit successfully. Therefore, the system can coexist with microwave ovens and can be used safely. Moreover, microwave ovens are not mobile whilst the patient will be mobile when using the wireless FES, therefore, the wireless FES will be exposed to microwave oven interference for a short period only, which reduces the chance to be exposed to its interference.

The last experiment in the laboratory investigated the effect of having the ZigBee module next to the stimulation output stage. As shown in the results, the system was not affected by the stimulation output. This is due to the fact that the stimulation signal is a significantly lower frequency signal (usually 40Hz) compared to the 2.4GHz band used by ZigBee devices. In addition to this, filters are selective on the ZigBee module to be able to work only on one ZigBee channel (5MHz bandwidth). And therefore other frequencies are filtered, including any radiation from the stimulator output stage.

Experiments ‘Interference free’, ‘Wi-Fi interference’, ‘Bluetooth interference’, and ‘Microwave oven interference’ included some trials in which the distribution of latency values formed two peaks within the interval 10 to 40ms. This was found only in the first trials of these experiments. This can be due to the collision avoidance mechanism described in the ZigBee protocol. This causes transmissions to back off for a random period of time if interference is detected, hence the two bands. However, this does not explain the fact that it appears only in some of the trials. This should be investigated as further work, since this work focuses on estimating the distribution of latency values compared to a maximum acceptable value.

The results from in vivo evaluation of the system on healthy volunteers are also encouraging with 100% reliability of reception and sustainable reliability higher than

99.94% of reception within 100ms. All results were obtained in realistic practical conditions with multiple interference sources and constantly changing environments. These results were better than the ones obtained in the laboratory with specific interference sources. Although the route chosen for this experiment included many sources of interference, the effect on the system was not as significant as the laboratory conditions. This supports the explanation mentioned earlier about real conditions in which the user moves and is not exposed continuously to high levels of interference. They can be close to a source of interference for a short period of time, but if they are moving, i.e. walking, they quickly increase the distance from the interference source, resulting in less interference.

6.3.2 Power consumption experiments

The footswitch battery exceeded the initial requirements of at least one day battery life. The battery, in the laboratory experiment, lasted for the equivalent of 41 days battery life based on 10,000 steps a day. However, due to the power consumption of the device when paused, which is not taken in consideration in this experiment, the battery life would be shorter than 41 days.

The feedback from patients, participating in the wireless footswitch trial, suggests that the battery, in the wireless footswitch, lasted for three weeks of daily use. This is comparable with the results of the laboratory tests. These results indicate that power consumption is sufficiently low to enable the device to be used clinically.

The experiment on the battery life of the stimulator, in the laboratory, suggested that the Alkaline PP3 battery used lasted over one day's worth. In real conditions, the battery lasted for one day and a half as reported by participants of the wireless footswitch trial. This is encouraging as it exceeds the initial specification which was one day of use, and therefore it enables the device to be suitable for clinical use.

From the laboratory experiments, the footswitch battery started to discharge faster when it reached 2.5v (Figure 5.12, Chapter 5). And in the stimulator, the battery started to discharge when it reached 6.3v (Figure 5.13, Chapter 5). These two levels were therefore used as thresholds to set the low battery alarm in both devices.

6.4 Wireless three-channel stimulator testing

Results of both experiments on healthy volunteers and the case study are encouraging, and showed that the proposed system can detect and enable the appropriate stimulation channels when given the right sensory input. Results also showed that the wireless three-channel system was clinically applicable. Healthy volunteers experiment showed that the control strategy was reliable and repeatable, since the system detected and enabled the appropriate channels. Channel 1 (drop foot stimulation) responded successfully to the events detected by the respective sensors for all participants. There was no record of any false positive or false negative event in this stimulation channel. In the other two channels, after analysing the graph of the output signals using Matlab, there was only eight false negatives and four false positives identified within a total of 1699 recorded events, i.e reliability of 99.29%. The other false events, as explained in the results, were due to the algorithm comparing the recorded stimulation triggering signals to the predicted ones. The latency in this situation was in the range of 200ms which would reflect on the response time of the system in this situation. However, a delay of 200ms is acceptable in these conditions since it affected only the first reaching sequence and would not create a risk for the patient.

Volunteer 5 had two false negatives in channel 2 (Triceps brachii stimulation), and as a result, two false negatives in channel 3 (Wrist/fingers extensors stimulation). These two events followed each other separated by 158ms. This would have triggered stimulation and stopped it in a short time equivalent to six stimulation pulses, given that the stimulated frequency was set to the commonly used standard stimulator frequency of 40Hz. Moreover, this was during standing/sitting mode which would be intended for reaching and grasping an object. Therefore, it is not long enough to have a functional benefit for reaching and grasping. Therefore, although the system missed triggering stimulation, this short stimulation burst would not have been beneficial and therefore not important in this case.

The four false positive events seen with volunteer 3 in channel 2 are unexpected and occurred at random timings. They caused stimulation to stop while reaching in channel 2 for only 200ms. This could affect the behaviour of the system in the following events, since the reaching sequence is considered complete only if uninterrupted for more than 2s. This occurrence was not seen in any of the data from other volunteers, and could not be repeated with both; other volunteers and when the experiment was repeated 30 times.

Moreover, this did not occur in channel 3 which is designed to follow channel 2 in standing/sitting mode. So, this was not caused by a failure in the control strategy and it could have been the result of a glitch in the microcontroller in channel 2.

Position and orientation of channel 2 is important for the triggering of reaching in standing/sitting mode as explained in Chapter 4. Some of the volunteers, while reaching for a high object, triggering of reaching stimulation did not respond accurately every time. This might be caused by the rotation of the arm (medial rotation), when reaching for a high object, observed with some volunteers, such as volunteer 4 as seen in Figure 6.2. This potentially changes the orientation of the accelerometer sensor, resulting in out of range operation of the accelerometer i.e. the x axis (the accelerometer axis used to detect shoulder flexion) is parallel to the floor. As a result, the system detects this as an end to the reaching attempt and stops stimulation as a result. The benefit of using one axis is a simple detection algorithm which looks for movement forward and backwards only. Although, it is unlikely that patients, suffering from upper limb impairment and who are targeted for the use of this device, will be able to achieve such high angles of shoulder flexion, a more complex sensory system should be investigated, such as combining a gyroscope with an accelerometer, to improve the accuracy of reaching attempt detection. On the other hand, the mis-trigger in these situations does not affect the effectiveness of the control system since when given an accurate input it generates a suitable output. In addition, patients' education and training would be necessary to enable them to achieve the optimal benefit.

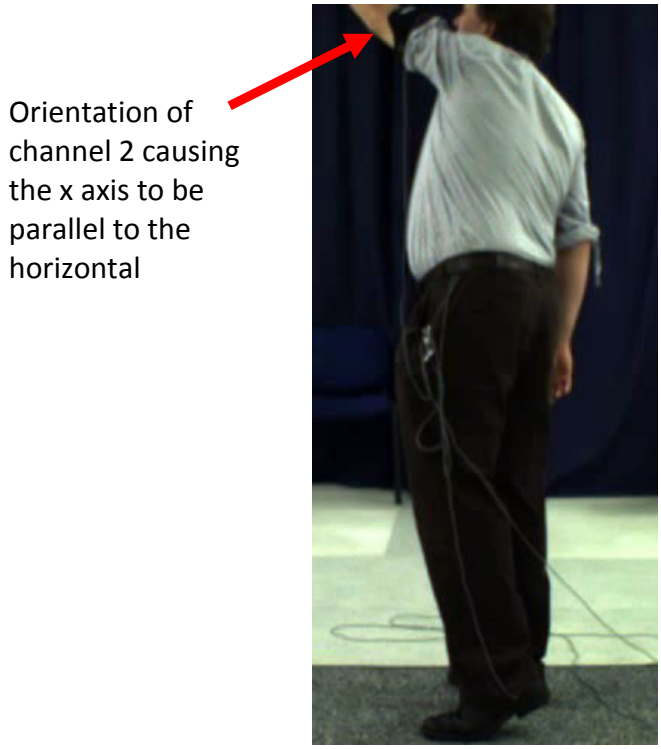


Figure 6.2: Medial rotation of the arm when reaching for a high object observed during one of the trials with volunteer 4.

The relatively higher number of events, in channel 2 and channel 3, found with volunteers 2 and 4 is also a consequence of the reaching sensor not working effectively. This might have been a result of the location of channel 2 moving around the arm after a sudden movement. Some of the volunteers, volunteers 2 and 4 in particular, were observed to move their upper limb rapidly when reaching (when flexing the shoulder and extending the shoulder). This was followed by a sudden stop which caused the movement of channel 2 around the arm. This can be seen in the accelerometer triggering trace shown in Figure 6.3, which shows the resulting glitches in the accelerometer activation signal. Although this situation should not occur with patients as they usually do not move that fast, as seen with the existing FES user who volunteered for the case study, this will be investigated further in future work to minimise this effect. The detection algorithm on this sensor is already designed to filter sudden movements when reaching, such as tapping the device, by taking two reading separated by 200ms to detect a reaching attempt. However, this seems to be insufficient to filter the events described above since there is no filtering in detection of inactivity. Therefore, the detection algorithm should be reviewed by filtering inactivity detection as done with

activity (reaching attempt detection), and/or integrate a gyroscope with the accelerometer, since the gyroscope on its own suffers from drift.

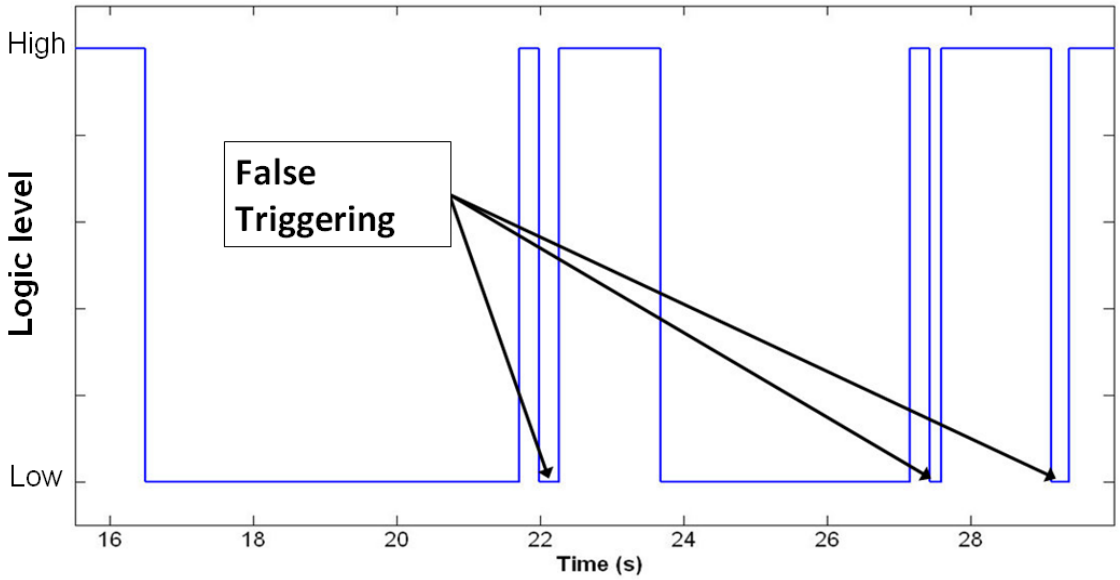


Figure 6.3: Sample from reaching activation signal collected with volunteer 4 recorded during two reaching forward attempts which shows two false triggering events.

As found in the case study (impaired volunteer), a personalised setup of the accelerometer threshold was necessary. Depending on the extent of the disability and the posture of the arm in the resting position, the thresholds should be different. The need for different threshold values was found even with the same volunteer. For instance, the thresholds were changed to suit the volunteer when the he was sitting. The ideal system would detect the need to change the threshold values to adapt to the need. This could be done by permanently tracking the acceleration values, or by having two presetting values; one for standing and the other for sitting. This would require a detection mechanism of standing and sitting. However, it would also be expected that the user would adapt to the system and would become more adapt at controlling it with more prolonged practice.

The preset time period of 3s on both accelerometers, in channel 1 and the Wireless FootSwitch (WFS), used to detect walking and stationary modes, was found slow for this particular volunteer. The volunteer (existing FES user) in particular, was a fast walker and was attempting reaching sooner than the system detected that he entered the stationary mode. However, for a slow walker, the values of periods of detection of stationary mode (set in these experiments to 3s in both the WFS and channel 1) would

need to be long. This would prevent the system from switching to stationary mode while the person is walking (caused by the relatively low accelerations). Therefore, these two periods should be set individually to the needs of a patient. And would therefore, be determined by the patient and the clinician when the system is set up.

Using the accelerometer in the WFS has shown a noticeable benefit to the function of the system. It eliminated the false positive stimulations that do occur while the patient transfers weight from one leg to the other whilst standing. This problem was reported in the literature as it causes discomfort to patients [57]. From the experiment with the patient in this project, it was clear that this problem could happen when attempting to reach for an object. This happens naturally due to weight transfer when moving the upper limb or attempting to reach, as the pressure on the FSR changes, causing the detection algorithm in the footswitch to report this as heel events. The proposed solution for this, worked effectively for all participants (healthy volunteers and the case study volunteer). This brought two advantages to the system. The first was that it prevented the system from generating unnecessary stimulation which would cause discomfort to the user. The second one was that it prevented the system from switching to walking mode, as a result of receiving a heel event which is only caused by a change of pressure on the FSR. This can be seen clearly in Figure 6.2 which shows the heel of the volunteer off the ground when reaching for a high object during one of the trials.

It was noticed from the case study, with the impaired volunteer, that as the experiment progressed, the movement of the upper limb of the volunteer improved. The volunteer was able to extend and open the hand without stimulation, to a certain extent, which allowed him to grab an object and releasing it without stimulation. This explains how the patient was able to release the object on the table, during the experiment, faster than the system could detect his intention, and as a result did not receive stimulation. This effect is described by Mann et al. [32] who suggest that FES has a training effect on patients who would be able to have some voluntary control over paralysed muscles after being stimulated.

6.5 Summary

The maximum acceptable latency was defined in this work as 100ms, as a result of the experiment of delayed stimulation. Further investigation on the effect of delayed stimulation on a larger group of patients is required.

The concept of a wireless FES system was shown to be feasible with performance that enables the system to be used clinically. This is a result of the high reliability, low latency and the low power consumption. The reliability and latency of the system met the specification, since the reliability approached 100% in all conditions and the latency was less than 100ms for over 99% of all transmissions. The power consumption of the system exceeded the specification in both laboratory and real conditions.

The three-channel stimulator worked successfully and showed high reliability and repeatability. It also showed the applicability of a wireless distributed FES system clinically, although it indicated the need to have sufficient flexibility in the system parameters in order to enable the system to be configured for each individual user. The control strategy designed for this system responded successfully to the sensory data. The system also successfully prevented unwanted stimulation when the user transfers weight from one leg to the other whilst standing, which occurs naturally when reaching for an object for example.

Chapter 7 - Conclusions and Future Work

This chapter summarises the work done in this research project and conclusions drawn from that.

7.1 Summary and conclusions from the literature review

Electrical Stimulation is an artificial technique to stimulate muscles to cause contraction. It is used functionally for patients with some neurological lesions such as Stroke and Multiple Sclerosis (MS). FES has been increasingly accepted as an orthosis which helps assisting and regaining some of the daily activities, such as walking. Nowadays, there is a range of FES applications available commercially. The most common is drop foot stimulation, which is characterised by a relative simplicity of control and sensing. However, patients could benefit from other applications such as reciprocal arm swing, and reaching and grasping stimulation. Ideally those functions would be integrated into a single system.

The current systems are mostly hardwired which is considered by some patients as unacceptable due to cosmetic or practical reasons. For instance, users found that the footswitch lead in the drop foot stimulator often makes dressing and undressing for the toilet difficult. Moreover, the wires are subject to wear and tear, causing reliability issues. The literature suggests two solutions for the issues found with hardwired systems. The first is using sensors that can be built in the stimulators which saves using wires. These sensors could be kinematic (accelerometers and gyroscopes) which can be used as tilt sensors or measure joint angles. However, for some applications such as walking, this type of sensor does not provide high accuracy in detecting gait events. The second solution consists in using a wireless network between the distal sensor and the stimulator. This has the advantage of using the best type of sensors and places them where needed without the inconvenience of wires. This approach was considered the best for this project and therefore the proposed application included a wireless network.

The wireless FES systems described in the literature were mainly for laboratory use and some required the use of a computer. These systems were centralised and used an

additional network node to manage the network traffic. There is only one commercial wireless system that is portable and does not use a central node (NESS L300, Bioness). Description of this system was not found in the literature and therefore no accessible evaluation of the performance of the wireless network of that system was available. For this reason, the first part of this research was dedicated to investigate the feasibility of a wireless FES system. This included identifying a suitable wireless technology and estimating the reliability, latency and battery life of the combined system.

The literature search focused on commercially available wireless technologies which can be used for FES in the clinical environment. The available technologies were personal area network standards such as ZigBee and Bluetooth. By comparing the specification of these standards, it was found that ZigBee was the most suitable for this application. ZigBee is a low cost, low bit rate, and reliable communication system. Commercial wireless modules based on this standard were identified and compared in terms of size, power consumption, and ease of use. The ZigBee module chosen for this research was the Telegisis ETRX3 which was small, low power, and allowed a wide range of control functionalities.

7.2 Wireless FES system

The first part of this project was investigating the feasibility of a wireless FES system which answers the first research question. A wireless drop foot stimulator prototype was designed and built to enable clinical evaluation. The prototype was used to measure the reliability, latency, and battery life to be compared to the expected specification. The system was first tested in the laboratory environment which allowed testing the system in controlled conditions. This resulted in identifying interference as the main problem that could face the proposed system. Therefore, the system was exposed to the most common sources of interference, and the reliability and latency were measured, both of which are affected by interference. Results of the experiments showed that Wi-Fi in some arrangements is the strongest source of interference. This caused the reliability to drop to 99.66% in 10,000 transmissions. Latency also increased on average when the system was exposed to interference. The maximum acceptable latency was determined experimentally by introducing a delay to the start of stimulation in a drop foot stimulator. The volunteers recruited for this experiment were current users of drop foot stimulator. The experiment showed that delays up to 100ms did not have a visible effect

on the gait pattern of the volunteers. Longer delays resulted in visible effect yet the stimulation was still safe. Following these findings, 100ms was considered as the maximum acceptable latency. Experiments have shown that latency did not exceed the defined limit for most transmissions, and the worst recorded performance of the system included only 0.33% of all transmissions, of one of the trials, received with latencies above 100ms. The experiments on the power consumption showed that the wireless footswitch could run on a single battery for up to 41 days, and the battery life in the stimulator was one day. The performance of the battery in the wireless footswitch exceeded the specification. As a result, the system was good to be tested in real conditions.

The system was tested on healthy volunteers who wore the system and walked with it in a combination of environments that included interference and open space. The reliability of the system was 100%, with 0.06% of transmissions above 100ms found with one of the volunteers. The initial results from the clinical trial of the wireless drop foot system also were encouraging. The current FES users who volunteered for this trial are positive about the system and have not reported major problems. These results were encouraging and met the specification. So in conclusion, a wireless FES system using ZigBee is feasible and can be used in every day activities. This led to the second part of the research presented in the following section.

7.3 Wireless distributed three-channel stimulator

The second part of the research was to implement the concept of a wireless multi-channel FES system for a specific application. The application was a three-channel stimulator used to coordinate both upper and lower limb function with automatic determination of stimulation channel selection. This required designing a control strategy that can detect predefined situations in which stimulation is needed. The control strategy chosen enabled drop foot and reciprocal arm swing stimulation when walking is detected. When stationary mode is detected, it enables reaching and grasping stimulation. The other novelty, included in this system, consisted of a walking detection mechanism in the wireless footswitch, which prevents unwanted stimulation when the user transfers weight from one leg to the other whilst standing. The system was tested first on healthy volunteers without applying stimulation. The experiments helped estimate the reliability and repeatability of the system with different volunteers.

Experimental results showed high repeatability and reliability of the control strategy. The system successfully identified the required stimulation channels with all volunteers. Furthermore, the case study experiment involving a current FES user, verified that the control strategy worked successfully on patients as well as on healthy volunteers. This case study also helped identify some potential improvements to the system, which consist of improving the algorithm of detection of reaching attempts, and introducing changeable settings of walk detection in both channel 1 and the wireless footswitch, in order to personalise the device to the needs of a given patient. The accelerometer thresholds used to trigger reaching were found to be different between sitting and standing. This requires further investigation to identify the ideal thresholds for both postures and to work out a mechanism to switch between the two.

The proposed solution to avoid false positive stimulation, using the accelerometer in the wireless footswitch, also performed reliably and prevented unwanted walking stimulation such as when attempting to reach. This technique could be included in current drop foot stimulators. This would improve the comfort of using FES systems for walking.

Going back to the second research question, this part of the project showed the feasibility of a three-channel stimulator that automatically enabled only the needed stimulation channels and prevented unwanted stimulation successfully. The control of the system was distributed which reduced the need for high computing power and long latencies. The system worked wirelessly which is more practical and would increase the acceptance of the device amongst patients.

7.4 Further work

In order to improve the reliability of the wireless drop foot stimulator even further, a predictive algorithm could be used to compensate for the missed events due to transmission failure. Initial tests had taken place on a relatively simple approach to prediction. This approach consisted of an algorithm that measures time between heel events (swing and stance phases) and intervene (predict an event) if an event is expected and the measured period exceeds the previous measured ones. This idea worked to a certain extent, especially when estimation of the period of prediction was based on an Infinite Impulse Response (IIR) filter type. However, delays were found when an event is missed while increasing walking speed. In addition, the system could generate false

positive stimulations, or predict an event earlier than the actual event, even though transmissions are not failing. This was found when walking was decelerating. As an improvement to this idea, the inbuilt accelerometers could be used to learn acceleration patterns while walking, which could be used to predict any missed event. This should perform better than the prediction based only on timing since it looks for current patterns of acceleration rather than use timings of previous steps. This will increase the overall reliability to achieve 100% reliability.

The three-channel stimulator proposed in this research could also benefit from some improvements in event detection. This concerns mainly detection of reaching attempts which could include an adaptive detection algorithm to estimate threshold values depending on the user's ability to flex their shoulder. This eliminates the problem of the need to change accelerometer thresholds when the posture changes, i.e. when the user is standing or sitting as found experimentally. Furthermore, detection of walking algorithm can be improved by defining experimentally the right accelerometer threshold values and the inactivity period. This requires a trial involving patients with different walking speeds. This will result in defining a set of accelerometer parameters to choose from, in both the wireless footswitch and drop foot nodes, to set up faster and reliable walking detection individually to each patient.

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Appendices

Appendix A: Confirmation for no need for NHS ethical approval

Dear Choukri

Thank you for your research protocol: Study of a wireless three channel stimulator for drop foot, arm swing, and hand opening (Nov 2011. v1)

The study is conducted in its entirety by OML and Bournemouth university staff. The Gait Lab in Salisbury district hospital will be used for the assessment as a (highly suitable!) place of convenience for all concerned.

I am please to inform you that, as the research is conducted outside of the NHS, you are not required to obtain NHS permission to proceed from Salisbury NHS Foundation Trust (R&D approval) not NHS research ethics committee approval. You may proceed locally once you have satisfied any requirements of Bournemouth University and OML.

I wish you every success with your project

With best wishes

Stef

Dr Stef Scott
Research Support Service (Salisbury) Manager
Research Design Service (SW) Consultant
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RDS-SW website: http://www.rds-sw.nihr.ac.uk/

Appendix B: Bournemouth University ethical approval

Bournemouth University

Initial Research Ethics Checklist

Note: ***All researchers*** must complete this brief checklist to identify any ethical issues associated with their research. Before completing, please refer to the BU *Research Ethics Code of Practice* which can be found www.bournemouth.ac.uk/researchethics. School Research Ethics Representatives (or Supervisors in the case of students) can advise on appropriate professional judgement in this review. A list of Representatives can be found at the aforementioned webpage.
Sections 1-5 must be completed by the researcher and Section 6 by School Ethics Representative/ Supervisor prior to the commencement of any research.

1 RESEARCHER DETAILS						
Name	Choukri Mecheraoui					
Email	*cmecheraoui@bournemouth.ac.uk*					
Status	☐ **Undergraduate**		☐ **Postgraduate**		☐ **Staff**	
School	☐ **BS**	☐ **AS**	☒ **DEC**	☐ **HSC**	☐ **MS**	☐ **ST**
Degree Framework & Programme	**PhD ESPRC CASE award**					
2 PROJECT DETAILS						
Project Title	Investigation of a networked wireless sensor system for multi-channel functional electrical stimulation in stroke patients.					
Project Summary *Sufficient detail is needed; include methodology, sample, outcomes etc*	This project investigates solutions for a new generation of multichannel Functional Electrical Stimulation (FES) systems. The developed system consists of a distributed wireless single stimulation channel and sensors. The control philosophy is designed to simplify the usability of these systems by detecting the physical intention of the user. Moreover, it efficiently uses the sensory data by sharing it with other channels requiring the same data.					
Proposed Start & End Dates	From 06/10/08 to 06/04/12					
Project Supervisor	Dr Jon Cobb and Professor Ian Swain					
Framework Project Co-ordinator	**N/A**					

3 ETHICS REVIEW CHECKLIST – PART A				
I	Is approval from an external Research Ethics Committee (e.g. Local Research Ethics Committee (REC), NHS REC) required/sought?		☐ **Yes**	☒ **No**
II	Is the research solely literature-based?		☐ **Yes**	☒ **No**
III	Does the research involve the use of any dangerous substances, including radioactive materials?		☐ **Yes**	☒ **No**
IV	Does the research involve the use of any potentially dangerous equipment?		☐ **Yes**	☒ **No**
V	Could conflicts of interest arise between the source of funding and the potential outcomes of the research? (see section 8 of BU Research Ethics Code of Practice).		☐ **Yes**	☒ **No**
VI	Is it likely that the research will put any of the following at risk:	Living creatures?	☐ **Yes**	☒ **No**
		Stakeholders?	☐ **Yes**	☒ **No**
		Researchers?	☐ **Yes**	☒ **No**
		Participants?	☐ **Yes**	☒ **No**
		The environment?	☐ **Yes**	☒ **No**
		The economy?	☐ **Yes**	☒ **No**

VII	Does the research involve experimentation on any of the following: Animals?	☐ Yes	☒ No
	Animal tissues?	☐ Yes	☒ No
	Human tissues (including blood, fluid, skin, cell lines)?	☐ Yes	☒ No
	Genetically modified organisms?	☐ Yes	☒ No
V111	Will the research involve prolonged or repetitive testing, or the collection of audio, photographic or video materials?	☒ Yes	☐ No
IX	Could the research induce psychological stress or anxiety, cause harm or have negative consequences for the participants or researcher (beyond the risks encountered in normal life)?	☐ Yes	☒ No
X	Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use, criminal activity)?	☐ Yes	☒ No
XI	Will financial inducements be offered (other than reasonable expenses/ compensation for time)?	☐ Yes	☒ No
XII	Will it be necessary for the participants to take part in the study without their knowledge / consent at the time?	☐ Yes	☒ No
XII	Are there problems with the participant's right to remain anonymous?	☐ Yes	☒ No
XIV	Does the research *specifically* involve participants who may be vulnerable?	☐ Yes	☒ No
XV	Might the research involve participants who may lack the capacity to decide or to give informed consent to their involvement?	☐ Yes	☒ No

4 ETHICS REVIEW CHECKLIST – PART B

Ethical Issue: The equipment used in this study is kite marked medical equipment and all testing will be carried out within the special facilities of the department of Medical Physics at Salisbury Hospital. In relation to item VIII above, two patient information/consent letters are attached and include a statement regarding the use of video in the experiments which participants will have to agree to by giving explicit consent.	**Action:** **Restricted approved test facility.** **Informed consent from participant for use of video.**

5 RESEARCHER STATEMENT

I believe the information I have given is correct. I have read and understood the BU Research Ethics Code of Practice, discussed relevant insurance issues, performed a health & safety evaluation/ risk assessment and discussed any issues/ concerns with a School Ethics Representative/ Supervisor. I understand that if any substantial changes are made to the research (including methodology, sample etc), then I must notify my School Research Ethics Representative/ Supervisor and may need to submit a revised Initial Research Ethics Checklist. By submitting this form electronically I am confirming the information is accurate to my best knowledge.

Signed	Choukri Mecheraoui	**Date**	**14th Oct 2011**

6 AFFIRMATION BY SCHOOL RESEARCH ETHICS REPRESENTATIVE/ SUPERVISOR

Satisfied with the accuracy of the research project ethical statement, I believe that the appropriate action is:

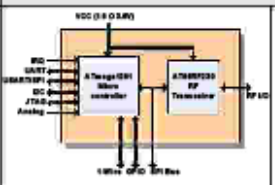
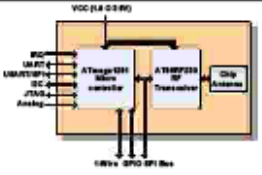
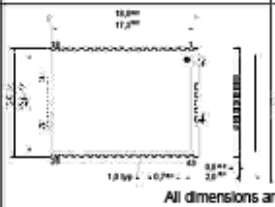
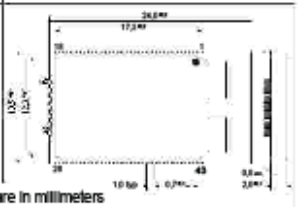
The research project proceeds in its present form	☒ Yes	☐ No
The research project proposal needs further assessment under the School Ethics procedure*	☐ Yes	☐ No
The research project needs to be returned to the applicant for modification prior to further action*	☐ Yes	☐ No

** The School is reminded that it is their responsibility to ensure that no project proceeds without appropriate assessment of ethical issues. In extreme cases, this can require processing by the School or University's Research Ethics Committee or by relevant external bodies.*

Reviewer Signature	(Prof Mark Hadfield)	**Date**	24/10/
Additional Comments			

Appendix C: ZigBit Datasheet

MeshNetics
Easy Wireless for Things

Parameter	ZigBit Module with Balanced RF Output (for Use with PCB Antenna / External Antenna)	ZigBit Module with Dual Chip Antenna
Part number	MNZB-24-B0	MNZB-24-A2
Module Operating Conditions		
Supply Voltage (Vcc)	1.8 to 3.6 V	
Current Consumption: RX/TX mode	19 mA/18 mA	
Current Consumption: Power Save /Deep Sleep Mode	6 uA/1.5 µA	
RF Characteristics		
Max Output Power	+3 dBm	
Receiver Sensitivity (PER 1%)	- 101 dBm	
Microcontroller Characteristics (AVR Atmega)		
On-Chip Flash Memory Size	128 kBytes	
On-Chip RAM Size	8 kBytes	
On-Chip EEPROM Size	4 kBytes	
Physical/Environmental Characteristics		
Size	18.8 x 13.5 x 2.8 mm 0.53? x 0.74?	24.0 x 13.5 x 2.8 mm 0.53? x 0.95?
Weight	1.3 g	1.5 g
Operating Temperature Range	-40°C to +85°C	
Block Diagrams		
Mechanical Drawings		
	All dimensions are in millimeters	
Availability	Mass produced & ready to order	

Low supply voltage (vs. standard 2.1v) extends battery life by as much as 20%.

Best in class sensitivity allows RF link ranges competitive with amplified modules. It ensures bidirectional RF link in the worst conditions.

More RAM means more robust stack performance and more space for user software applications.

Ultra compact size for easy integration.

Stable operation through the indicated temperature levels.

PRECISION MANUFACTURED IN GERMANY

MeshNetics

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Distributed by:

Appendix D: ETRX3 Datasheet

telegesis

ZigBee Member

ETRX357
ZigBee™ Module

Image not shown actual size; enlarged to show detail.

The Telegesis ETRX351 and ETRX357 modules are low power 2.4GHz ZigBee modules, based on the latest Ember EM351 and EM357 single chip ZigBee™ / IEEE802.15.4 solution.

They have been designed to be integrated into any device without the need for RF experience and expertise. Utilizing the EmberZNet ZigBee stack, the ETRX35x enables you to add powerful wireless networking capability to your products and quickly bring them to market.

The module's unique AT-style command line interface allows designers to quickly integrate ZigBee technology without complex software engineering. For custom application development the ETRX35x series integrates with ease into Embers InSight development environment.

Module Features

- Small form factor, SMT module 25mm x 19mm
- Side Castellations for easy soldering
- 2 antenna options: Integrated chip antenna or U.FL coaxial connector
- Industries first ARM® Cortex-M3 based family of ZigBee modules
- Industry standard JTAG Programming and real time network level debugging via the Ember InSight Port
- 192kB (ETRX357) flash and 12kbytes of RAM
- Lowest Deep Sleep Current of sub 1µA and multiple sleep modes
- Wide supply voltage range (2.1 to 3.6V)
- Module ships with Telegesis AT-style command interface based on the ZigBee PRO feature set
- Can act as an End Device, Router or Coordinator
- 24 general-purpose I/O lines including analogue inputs (all GPIOs of the EM35x are accessible)
- Firmware upgrades via serial port or over the air (password protected)
- Hardware supported encryption (AES-128)
- CE and FCC compliance, FCC modular approval pending
- Operating temperature range: -40°C to +85°C
- Long Range version with a link budget of up to 124dB available in the same form factor

Radio Features

- Based on the Ember EM351 and EM357 single chip ZigBee™ / IEEE802.15.4 solutions
- 2.4GHz ISM Band
- 250kbit/s over the air data rate
- 16 channels (802.15.4 Channel 11 to 26)
- +3dBm output power (+8dBm in boost mode)
- High sensitivity of -99dBm (-101dBm in boost mode) typ. @ 1% packet error rate
- RX Current: 25mA, TX Current: 31mA at 3dBm

Suggested Applications

- AMR – ZigBee Smart Energy applications
- Wireless Alarms and Security
- Home/Building Automation
- Wireless Sensor Networks
- M2M Industrial Controls
- Lighting and ventilation control
- Remote monitoring
- Environmental monitoring and control

Development Kit

- New Development kit containing everything required to set up a mesh network quickly and evaluate range and performance of the ETRX35x and its long range version.
- AT-style software interface command dictionary can be modified for high volume customers.
- Custom software development available upon request.

Example AT-Style Commands

AT+BCAST	Sends a Broadcast
AT+UCAST:<address>	Sends a Unicast
AT+EN	Establish PAN network
AT+JN	Join PAN

At power-up the last configuration is loaded from non-volatile S-Registers, which can eliminate the need for an additional host controller.

Telegesis
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Appendix E: Renata CR2430 Datasheet

the swiss power source

renata batteries

CR2430

3V Lithium Battery
Swiss Made

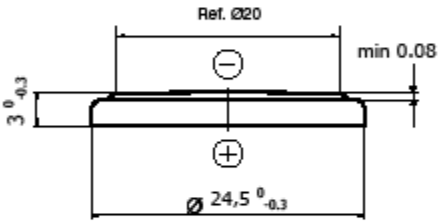
Technical Data Sheet

Specifications

Chemical System	Li / MnO_2
Nominal Voltage	3 V
Rated Capacity	285 mAh
Standard Discharge Current	0.5 mA
Max. Cont. Discharge Current	4.0 mA
Average Weight	4.1 g
Operating Temperature*	-40 - +85 °C
Self Discharge at 23°C	< 1% / year

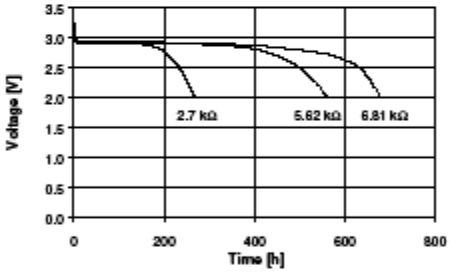
Dimensions

(According to IEC 60086)

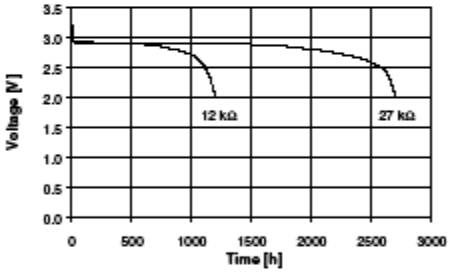


Performance

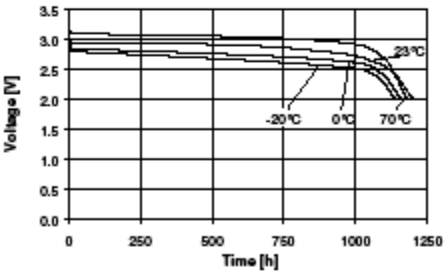
Discharge performance at 23°C



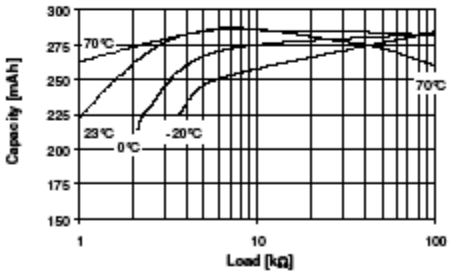
Discharge performance at 23°C



Temperature performance Load 12kΩ



Cell capacity at various loads



In applications where the battery is exposed to temperatures above 70 °C, please contact Renata for consultancy.

Information and contents in this data sheet are for reference purpose only. They do not constitute any warranty or representation and are subject to change without notice. For most current information and further details, please contact your Renata representative.

Rev. CR2430, 06 / 12.06

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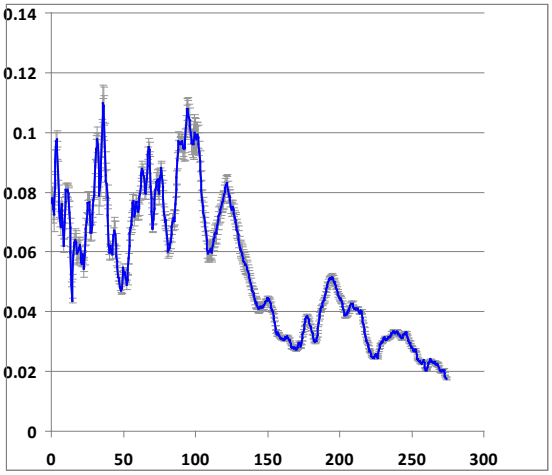
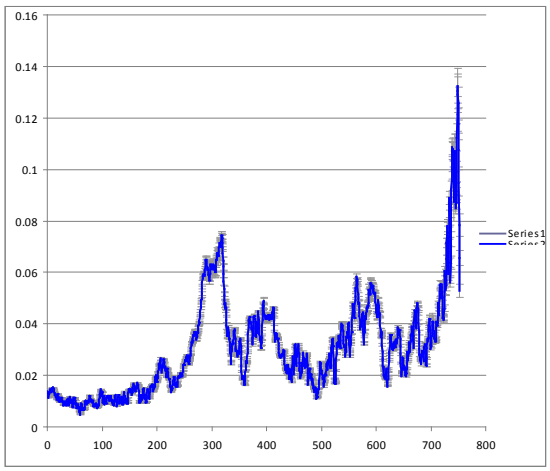
A COMPANY OF THE SWATCH GROUP

Appendix F: Graphs of the dorsiflexion timings experiment

Volunteer 1 – Normal walking speed

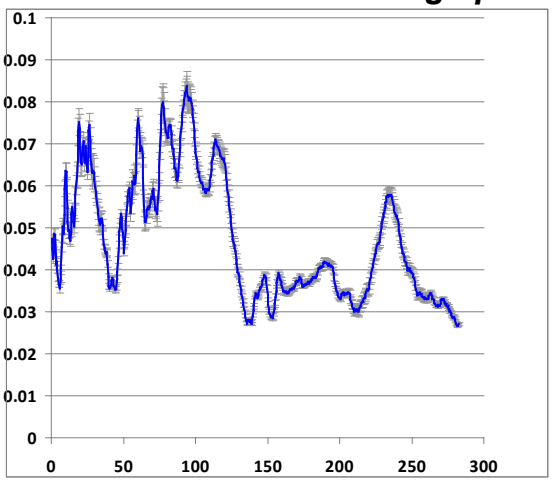


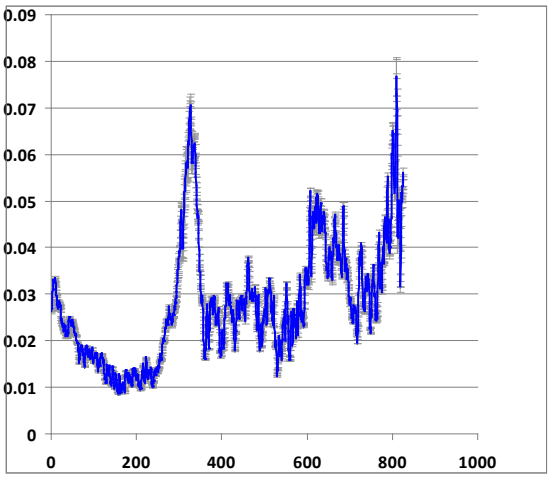


Stance (heel strike to heel rise) Swing (heel rise to heel strike)

Rectified EMG signal (v) vs Time (ms)

Volunteer 1 – Slow walking speed

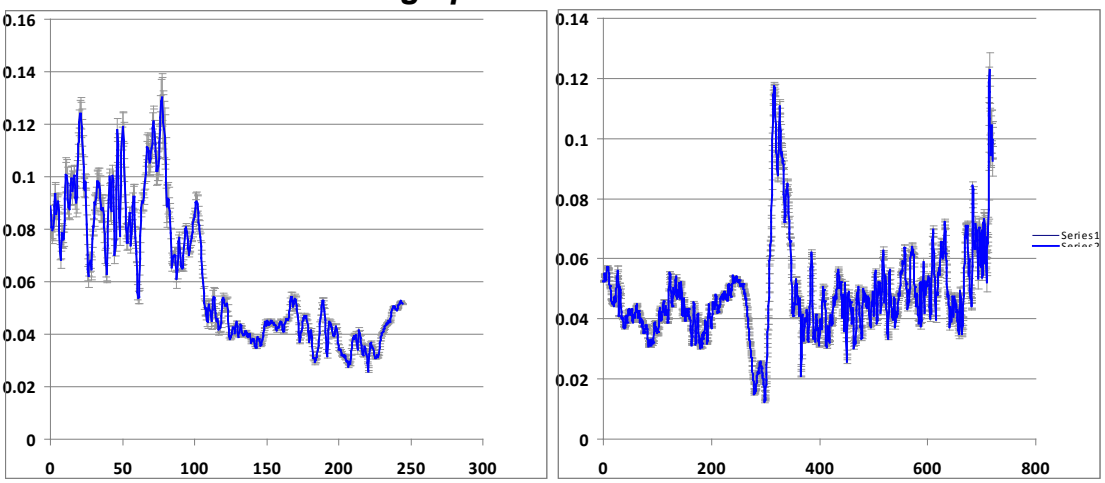




Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

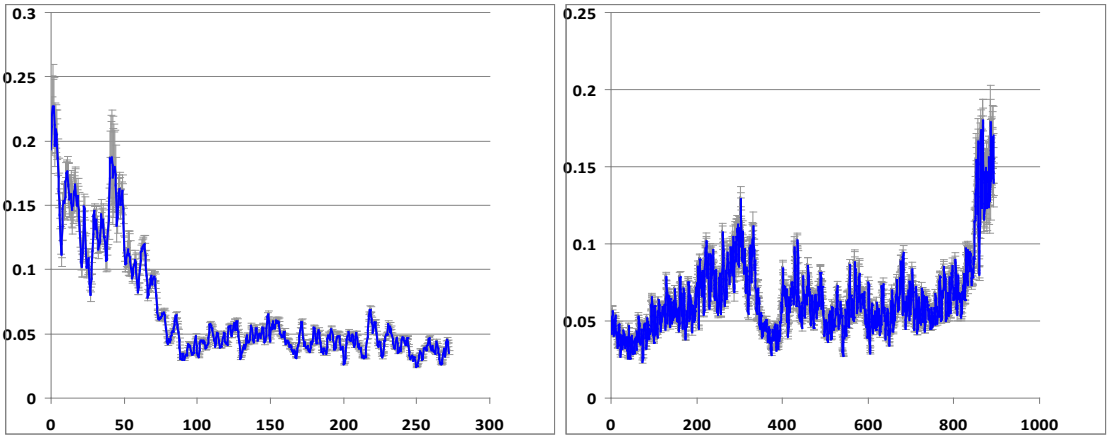
Volunteer 1 – Fast walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

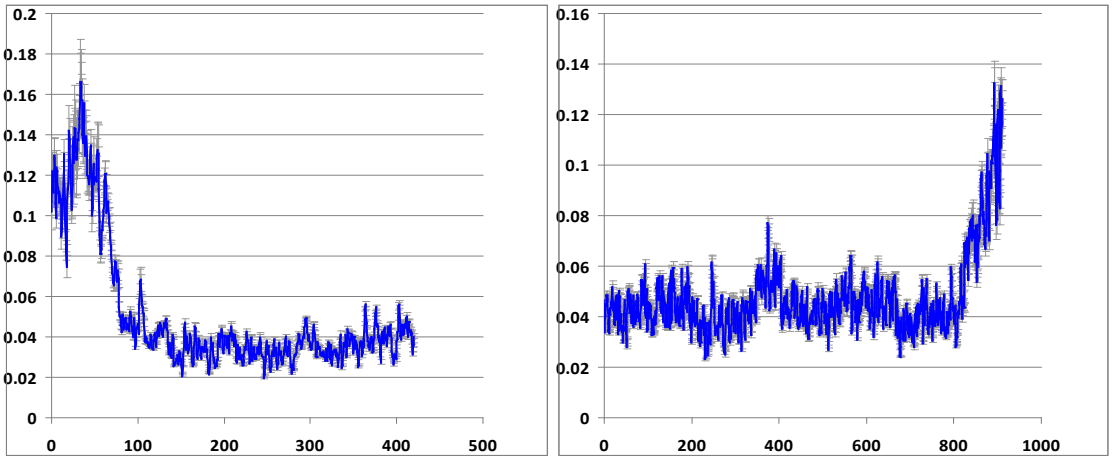
Volunteer 2 – Normal walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

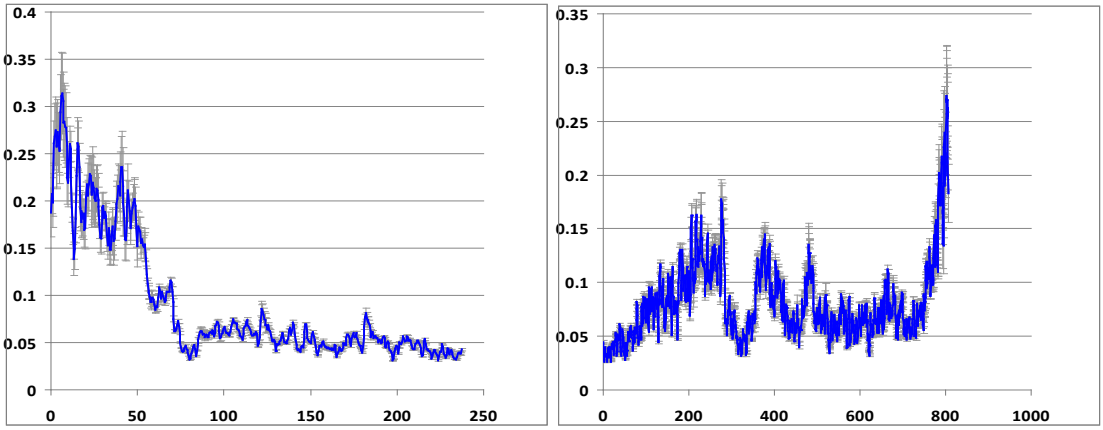
Volunteer 2 – Slow walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

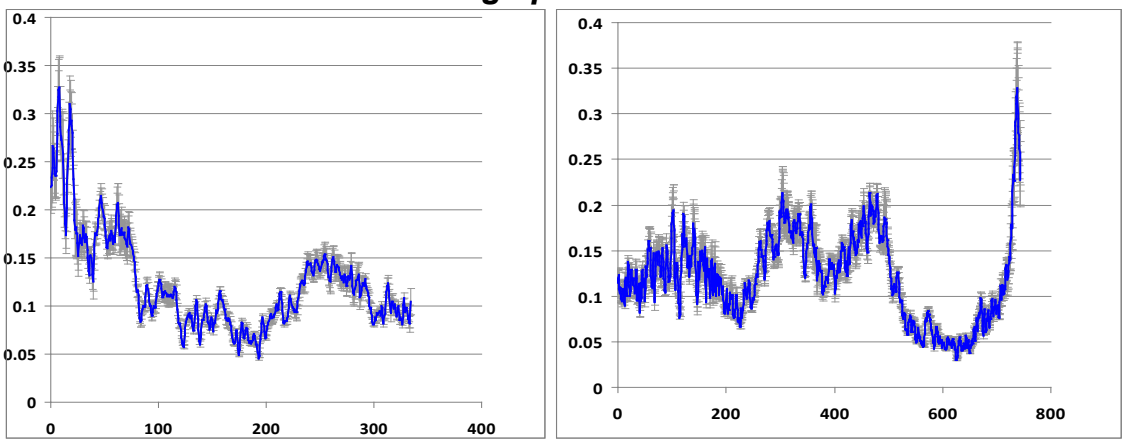
Volunteer 2 – Fast walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

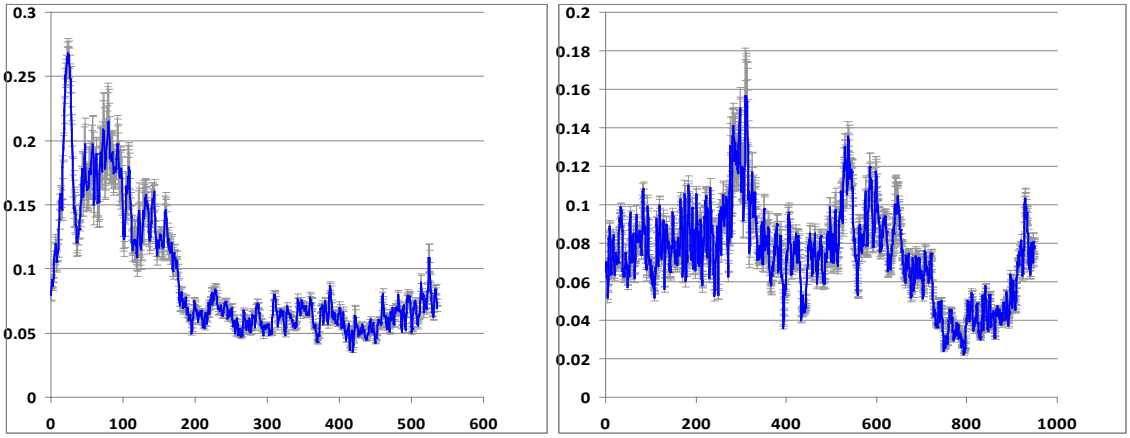
Volunteer 3 – Normal walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

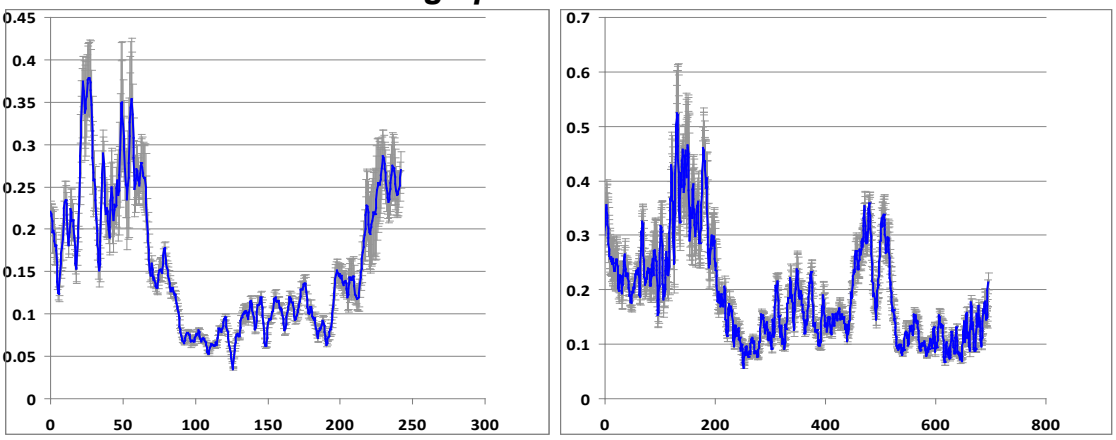
Volunteer 3 – Slow walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

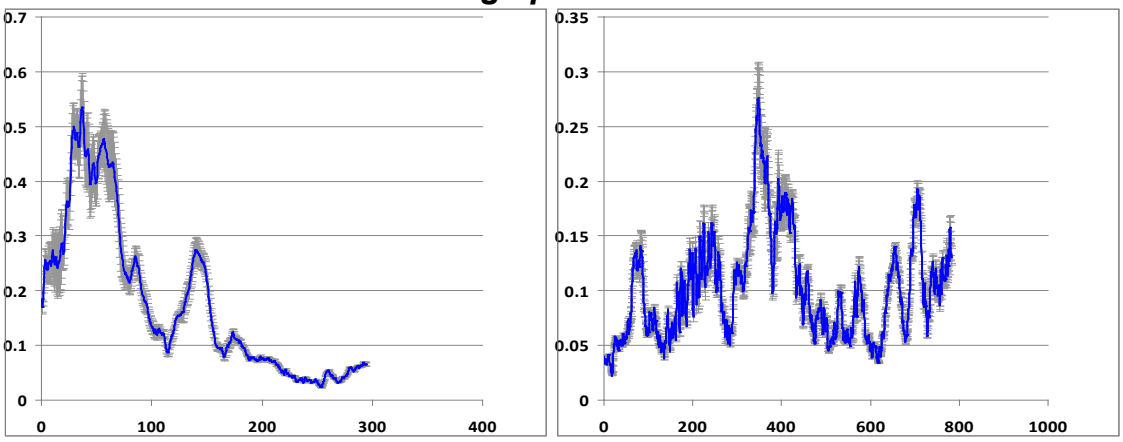
Volunteer 3 – Fast walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

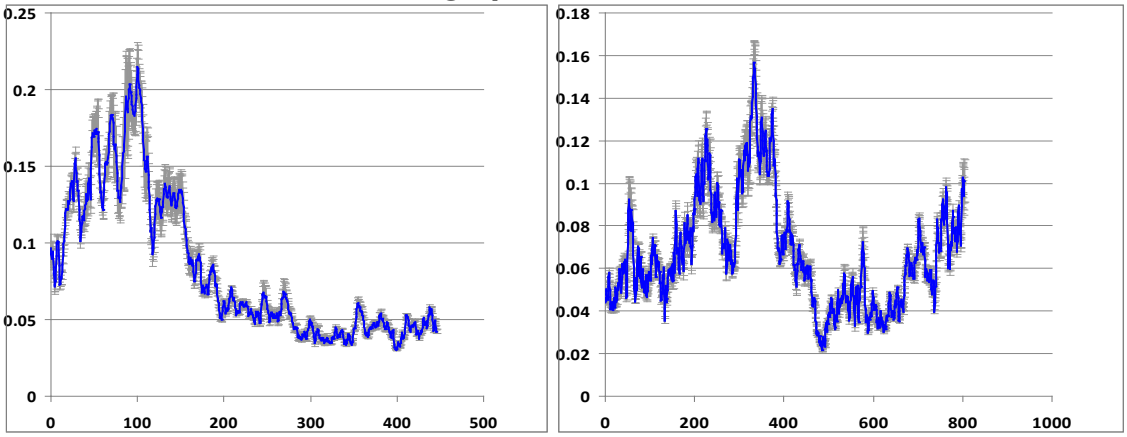
Volunteer 4 – Normal walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

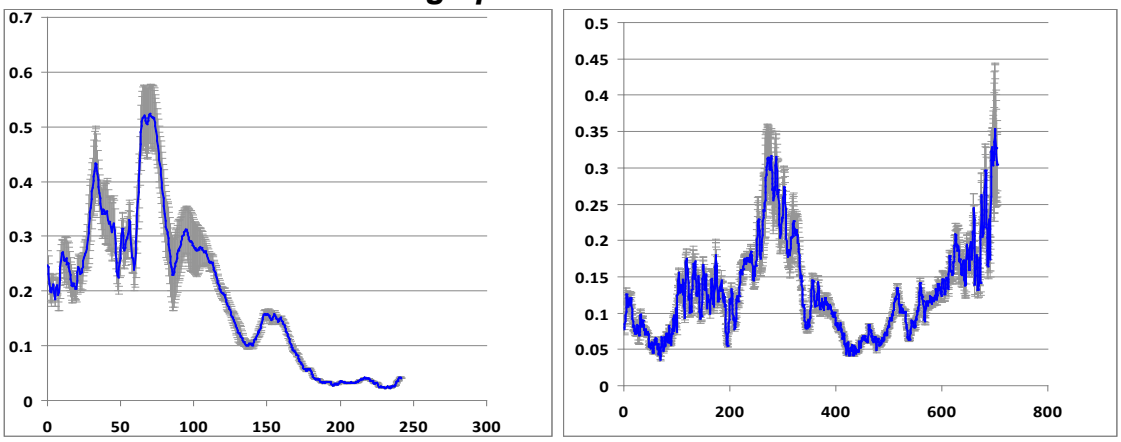
Volunteer 4 – Slow walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

Volunteer 4 – Fast walking speed



Stance phase Swing phase

Rectified EMG signal (v) vs Time (ms)

Appendix G: Latency values and distribution – Bench tests

This appendix includes graphs of the results of the reliability and latency experiments performed on wireless drop foot system performed in laboratory conditions.

Evaluation with Wi-Fi interference:

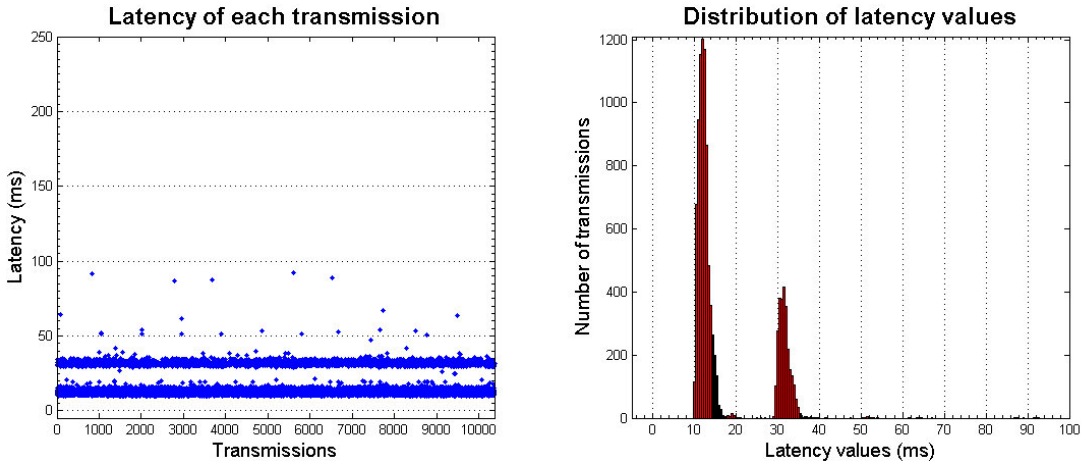


Figure A: Latency values and distribution (Trial 1)

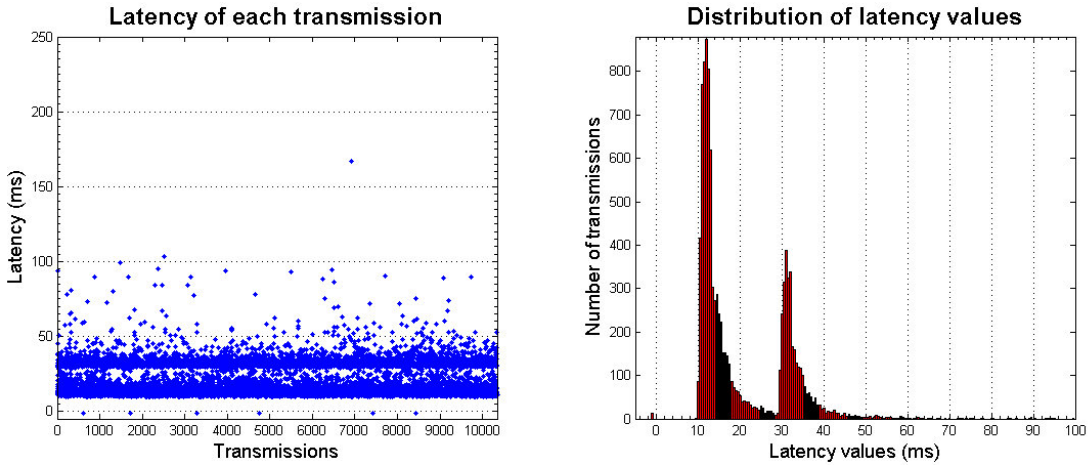


Figure B: Latency values and distribution (Trial 2)

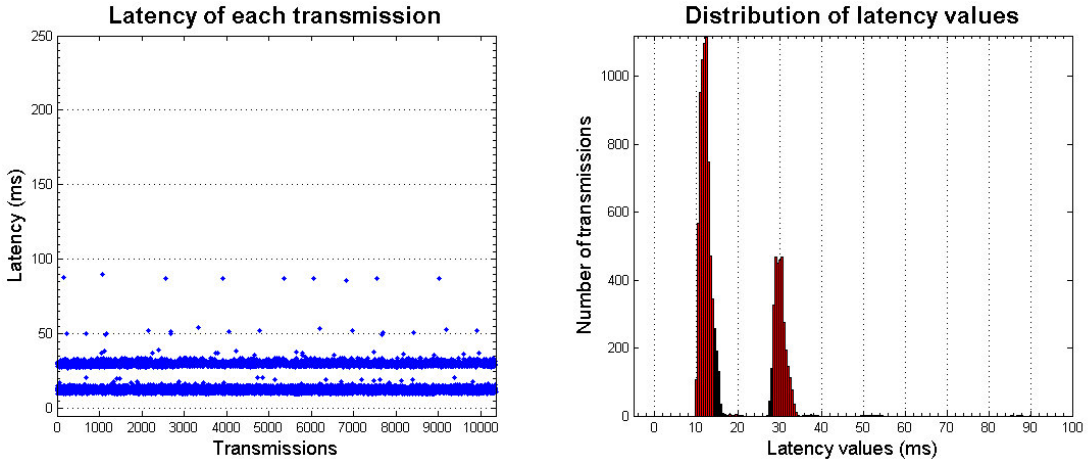


Figure C: Latency values and distribution (Trial 3)

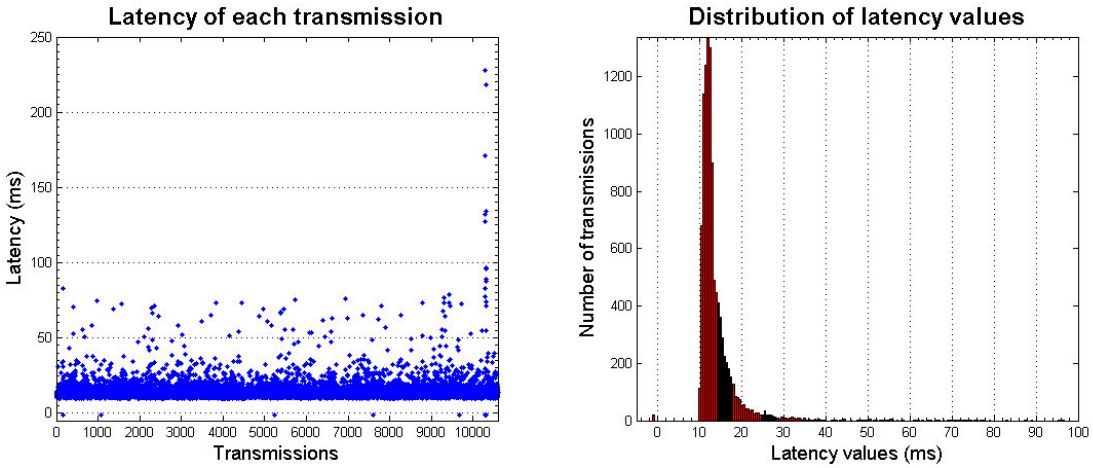


Figure D: Latency values and distribution (Trial 4)

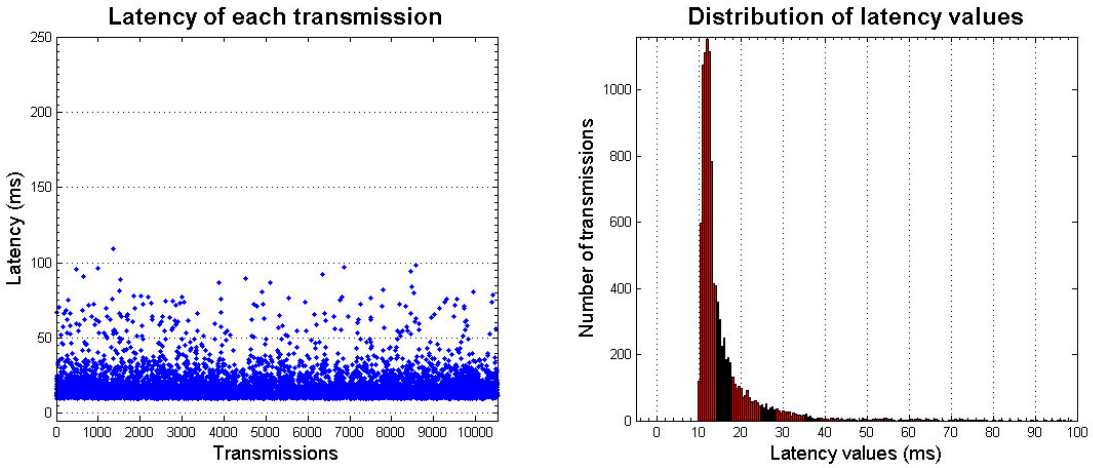


Figure E: Latency values and distribution (Trial 5)

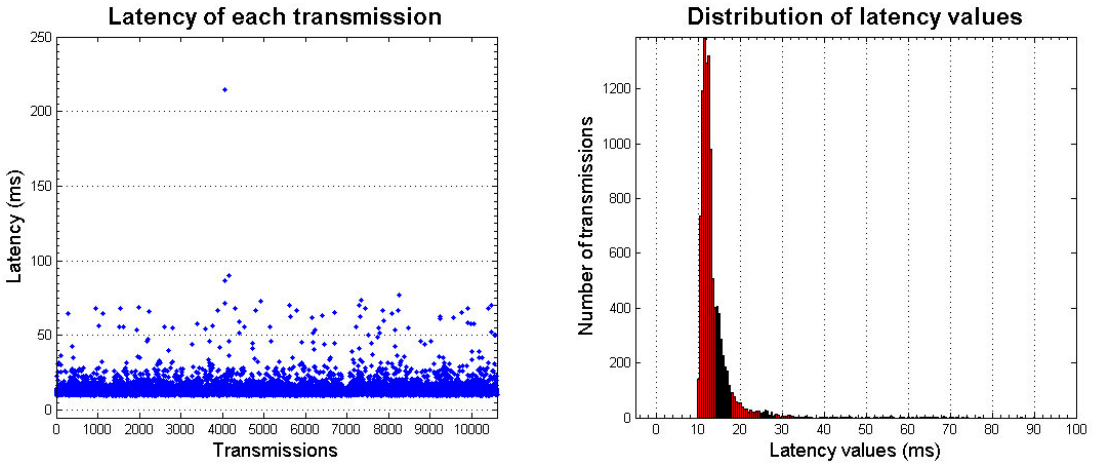


Figure F: Latency values and distribution (Trial 6)

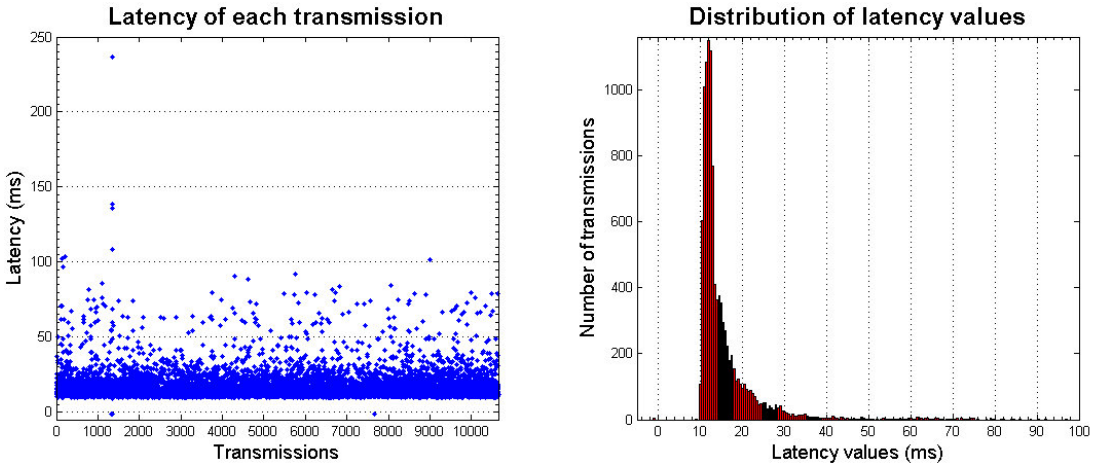


Figure G: Latency values and distribution (Trial 7)

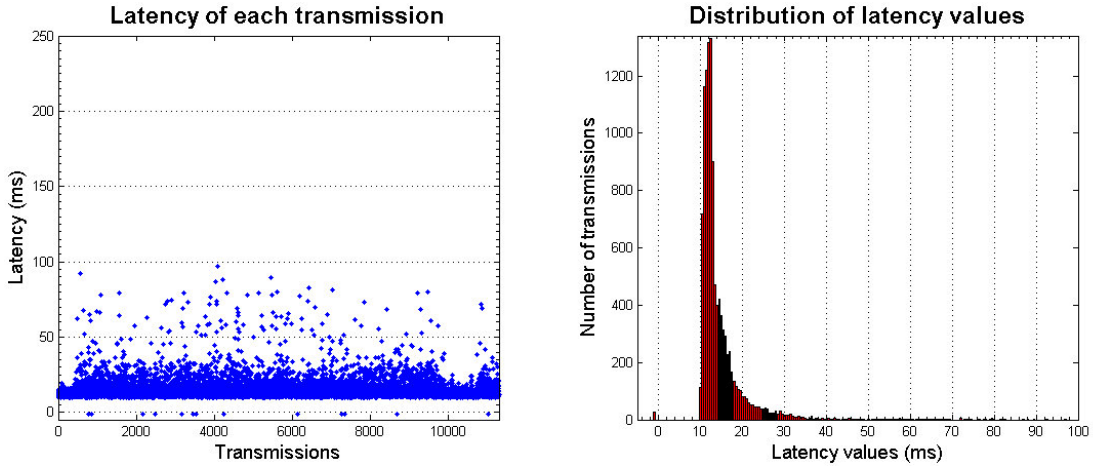


Figure H: Latency values and distribution (Trial 8)

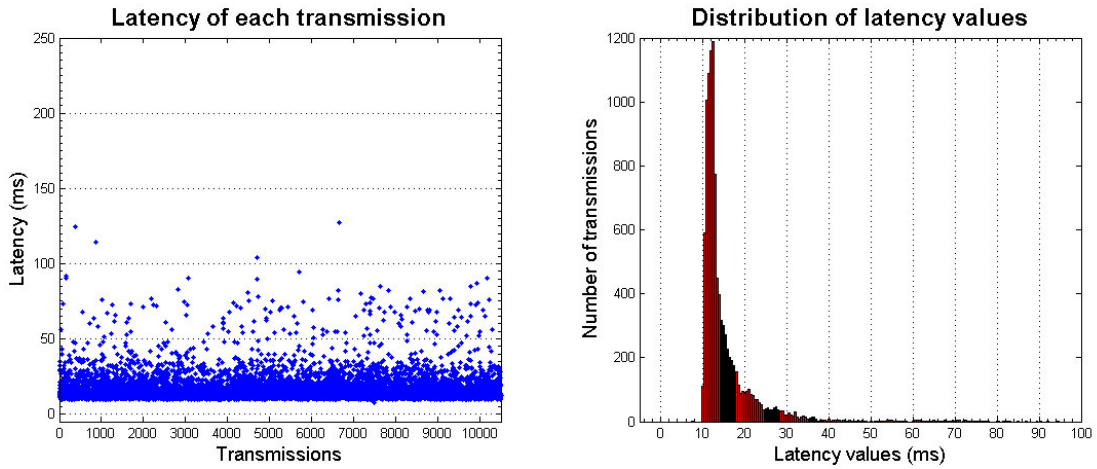


Figure I: Latency values and distribution (Trial 9)

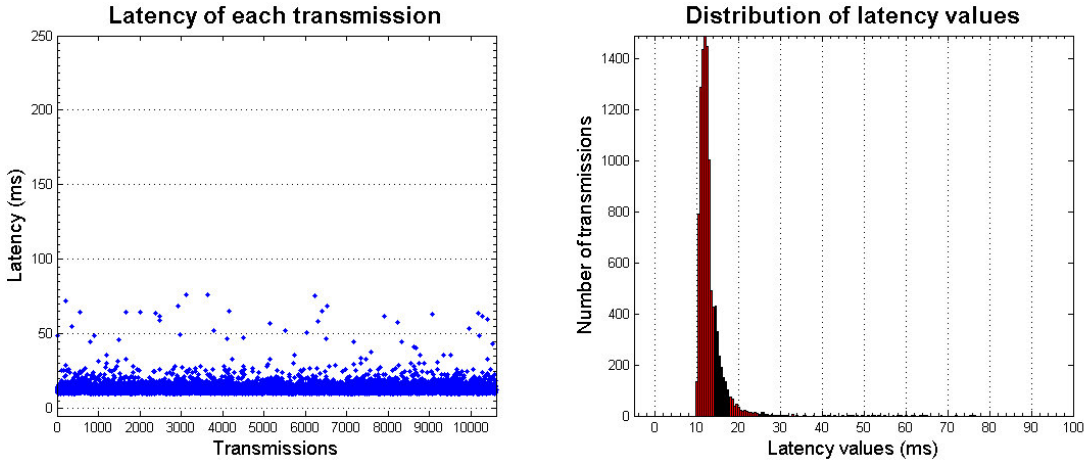


Figure J: Latency values and distribution (Trial 10)

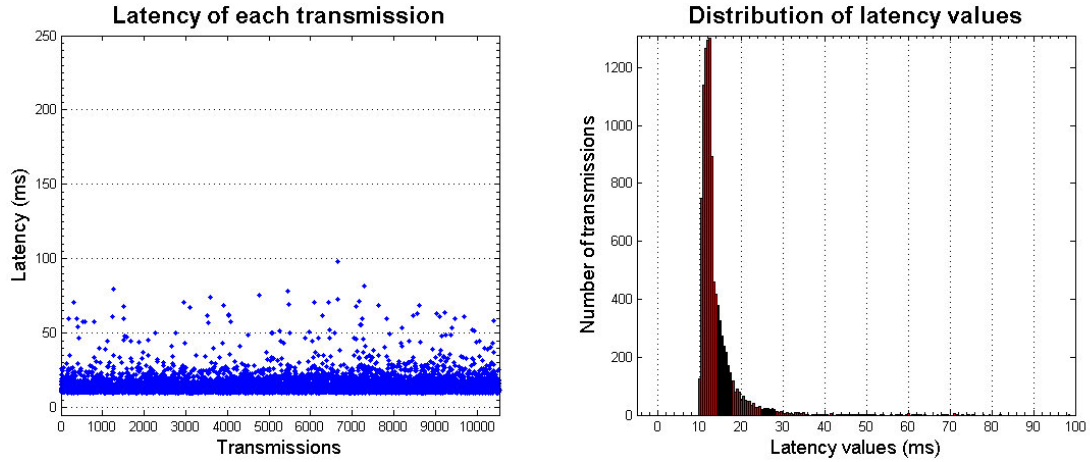


Figure K: Latency values and distribution (Trial 11)

Bluetooth interference experiment:

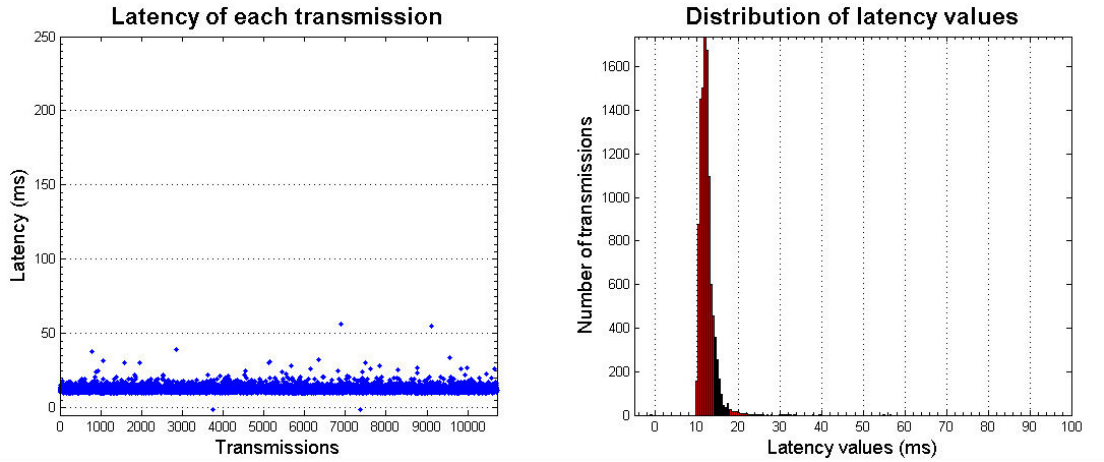


Figure L: Latency values and distribution (Trial 2)

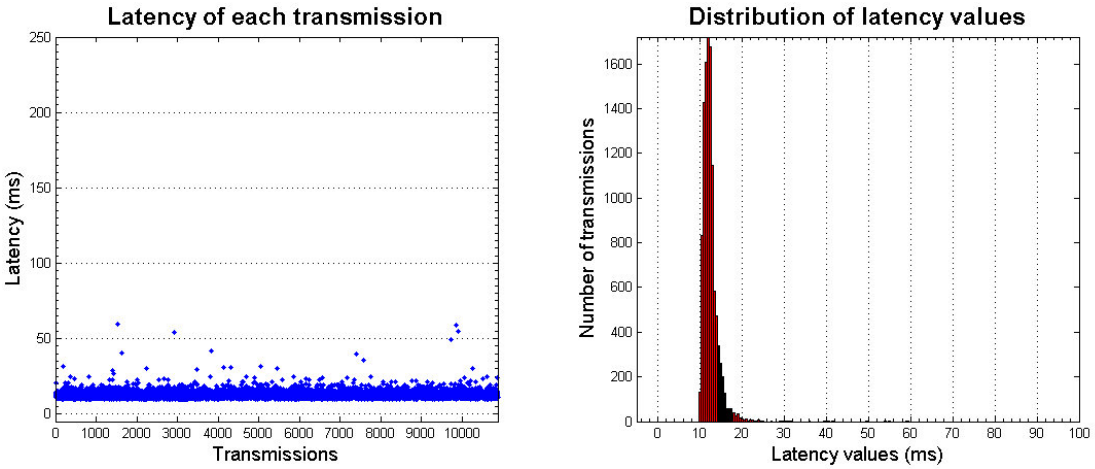


Figure M: Latency values and distribution (Trial 3)

ZigBee interference experiment:

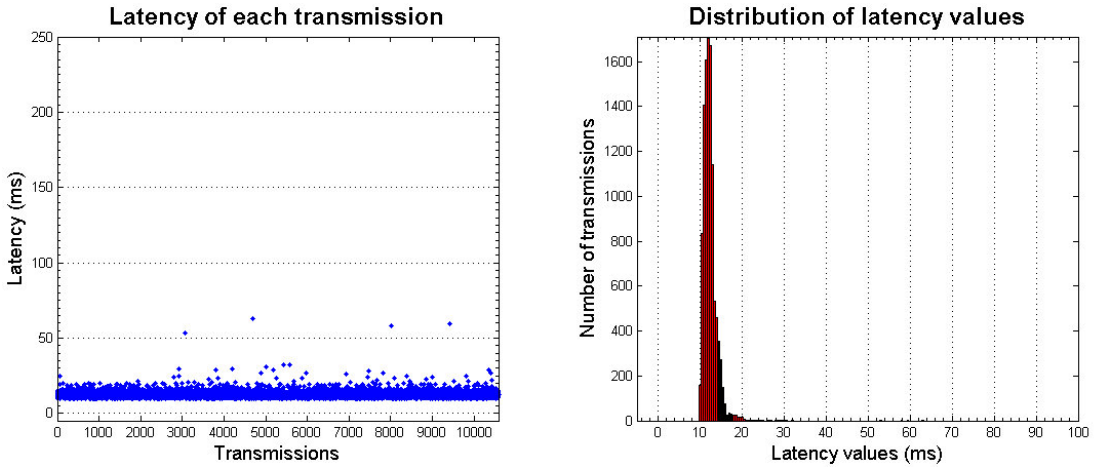


Figure N: Latency values and distribution (Trial 1)

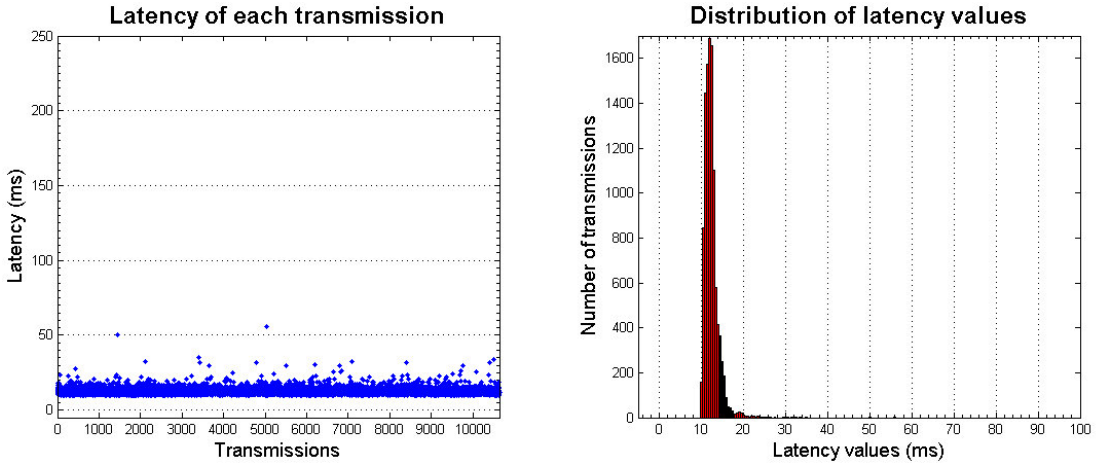


Figure O: Latency values and distribution (Trial 2)

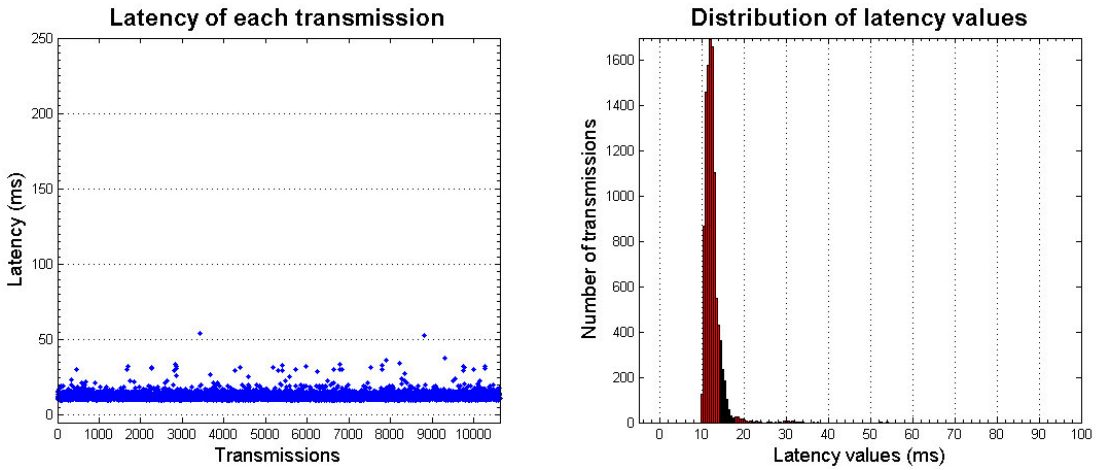


Figure P: Latency values and distribution (Trial 4)

Microwave oven interference experiment:

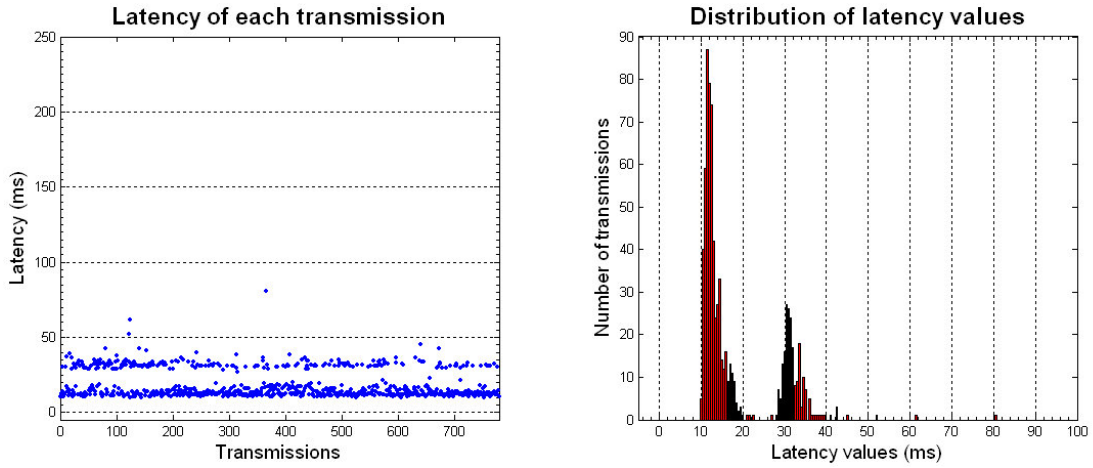


Figure Q: Latency values and distribution (Trial 1)

Appendix H: Reliability and latency results – Real world conditions

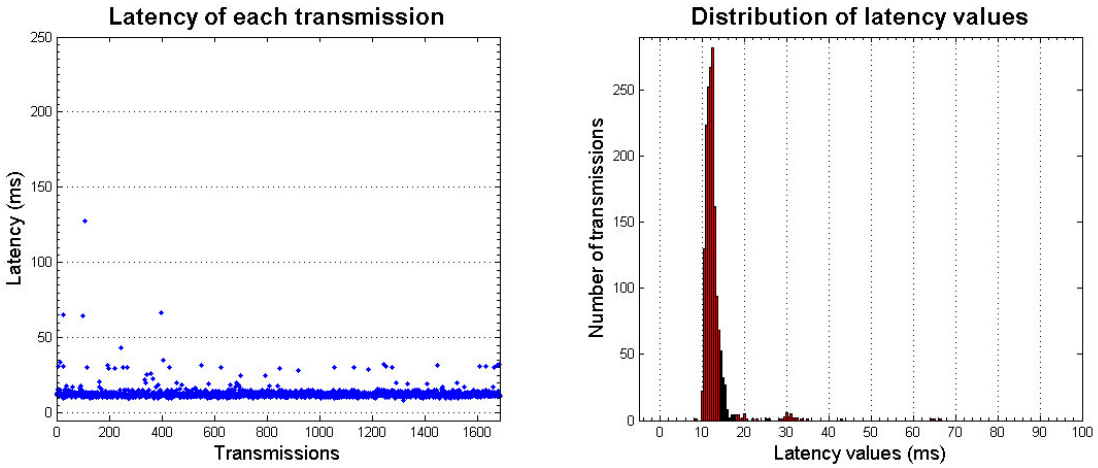


Figure A: Latency values and distribution (Volunteer 1)

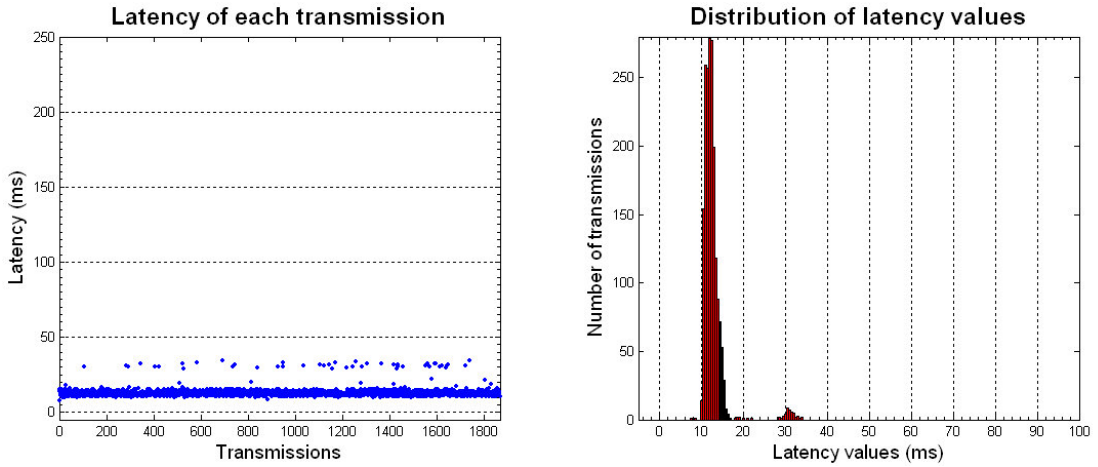


Figure B: Latency values and distribution (Volunteer 2)

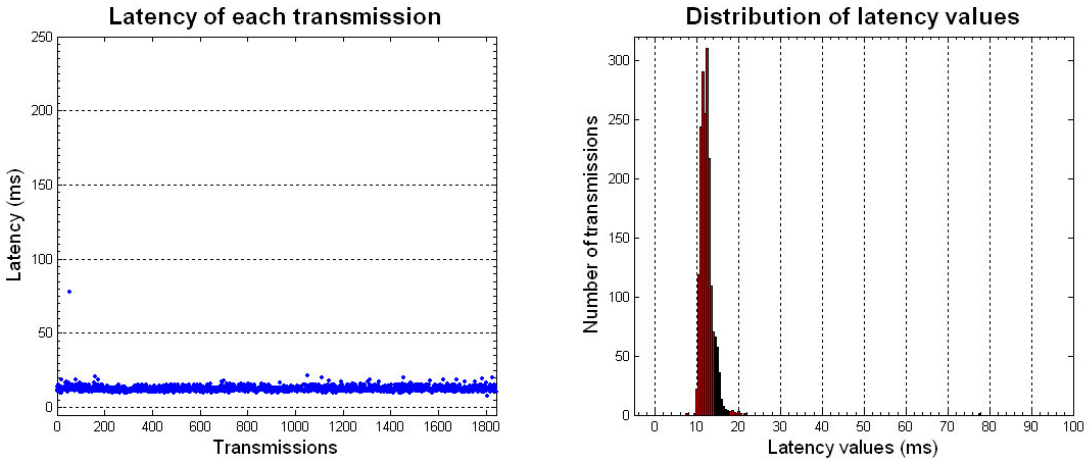


Figure C: Latency values and distribution (Volunteer 3)

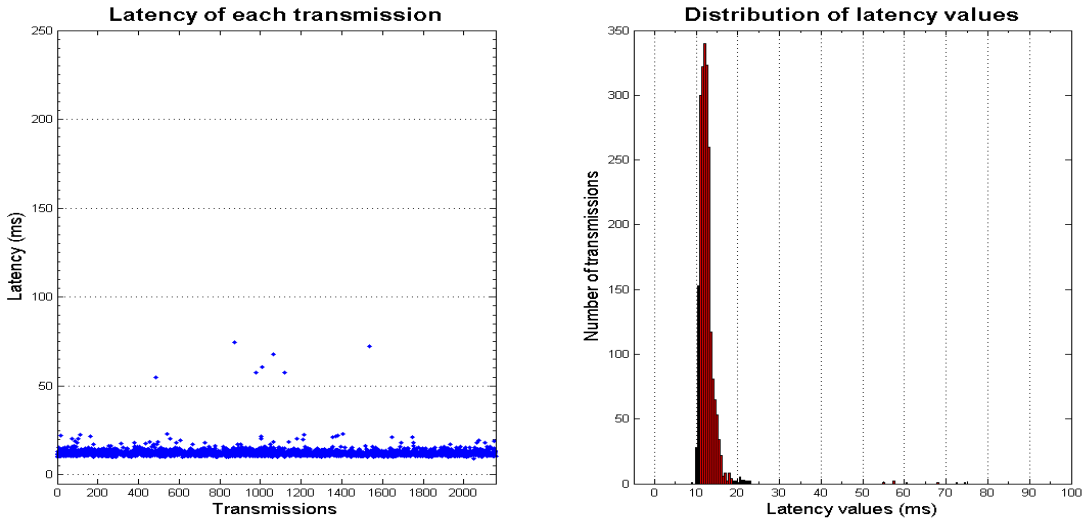


Figure D: Latency values and distribution (Volunteer 4)

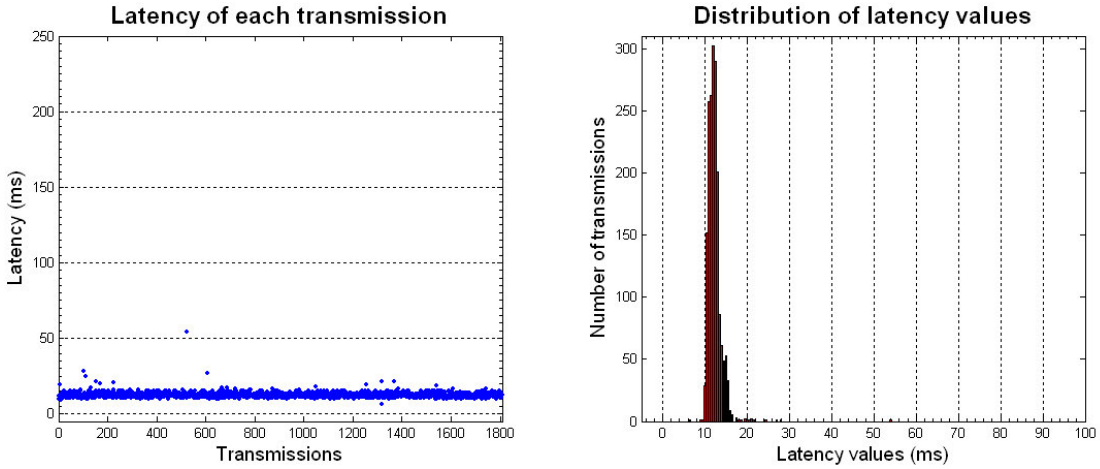


Figure E: Latency values and distribution (Volunteer 5)

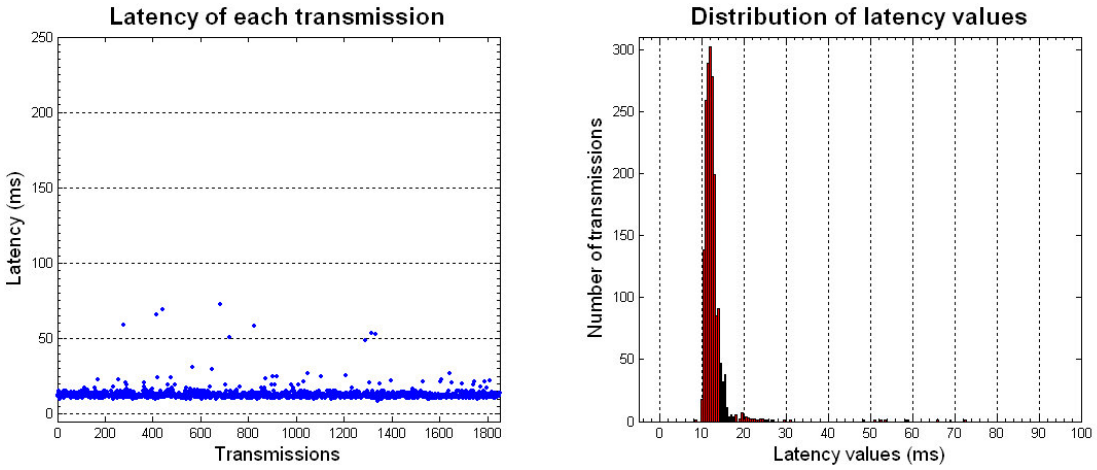


Figure F: Latency values and distribution (Volunteer 6)

Appendix I: Delayed stimulation experiment – Feedback (patient and clinician)

Feedback sheet

Volunteer: DS02

Session: A

Clinician: PT

Date: 02/08/11 Time: 12:00

Pace: SN2537 P22 Software (Pace): 11713_CM

Clinician's feedback

Scoring is on a scale from 1 to 10 where 1 is for unsatisfied and 10 for satisfied with stimulation.

Trial	Introduced delay (ms)	Clinician's score	Walking Speed
1	0	7/10	
2	25	8/10 (smoother)	12.00
3	50	7/10 (slightly slow)	11.20
4	75	7/10 (slightly slow)	11.05 10.90
5	100	7/10 (slight scuff)	10.70 10.50
6	150	7/10 (looked ok, less scuff)	10.80 11.10
7	200	6/10 (Less eversion + less stable)	10.2
8	250	6/10More circumduction (hip hitch)	10.6 10.7
9	0	8/10	10.1 10.6

Comments:

Patient's feedback (DS02)

Scoring is on a scale from 1 to 10 where 1 is for unsatisfied and 10 for satisfied with stimulation.

Trial	Introduced delay (ms)	Patient's score
1	0	7 or 8
2	25	(Slower and heavier) 6 or 7
3	50	(same as trial 2) 6 or 7
4	75	(same as trial 2) 6 or 7
5	100	(foot not clearing the floor very well) 6
6	150	(foot not clearing the floor very well) 6
7	200	(felt better than trial 6) 7
8	250	(Less dorsiflexion) 6
9	0	7

Comments:

Feedback sheet

Volunteer: DS03

Session: A

Clinician: IS

Date: 02/08/11 Time: 16:30

Pace: SN2537 P22 Software (Pace): 11713_CM

Clinician's feedback

Scoring is on a scale from 1 to 10 where 1 is for unsatisfied and 10 for satisfied with stimulation.

Trial	Introduced delay (ms)	Clinician's score	Walking Speed
1	0	9/10	10.97 11.24
2	25	9/10	11.11 11.10
3	50	9/10	10.17 10.99
4	75	9/10	10.43 11.67
5	100	8/10 (more inversion)	10.70
6	150	7/10 (more inversion)	10.49 10.13
7	200	6/10 (more drop foot + inversion)	10.87 11.10
8	250	4/10 (foot catch, hip hitch)	11.85
9	0	9/10	10.67

Comments:
Very slight difference up to 150ms but much more …. At 200ms + at 250ms foot caught 2 or 3 times.

Patient's feedback (DS03)

Note: this particular patient used a different scoring system. The first trial (no delay) was used as a reference with a score of 5. A higher score was given to a better stimulation and less than 5 if stimulation was not as good as the reference.

Trial	Introduced delay (ms)	Patient's score
1	0	5
2	25	6 (Felt better than the first)
3	50	7 (felt better than trial 2)
4	75	7 (Felt the same as trial 3)
5	100	8 (Felt better than trial 4)
6	150	5 (more effort)
7	200	5 (same as trial 6)
8	250	3 (worst so far)
9	0	5 (same as the first trial)

Comments:

Feedback sheet

Volunteer: DS04

Session: A

Clinician: IS

Date: 18/10/11 Time: 14:00

Pace: SN2537 P22 Software (Pace): 11713_CM

Clinician's feedback

Scoring is on a scale from 1 to 10 where 1 is for unsatisfied and 10 for satisfied with stimulation.

Trial	Introduced delay (ms)	Clinician's score	Score
1,2	0	Good correction – foot lifts … - good heel strike	8
3,4	25	Could not see any difference	8
5,6	50	Still no difference	8
7,8	75	Same as before	8
9,10	100	Possibly very slight slower pickup	7.5
11,12	150	Slightly less dorsiflexion and slow pitck up	7
13,14	200	Slower pick up – more compensation – less dorsiflexion	6
15,16	250	Starting to get inversion in swing – still safe – still heel strike	5
17,18	0	Back to original – no inversion	8

Patient's feedback (DS04)

Scoring is on a scale from 1 to 10 where 1 is for unsatisfied and 10 for satisfied with stimulation.

Trial	Introduced delay (ms)	Patient's comments	Score	Walking speed (s)
1,2	0	Usual stimulation	10	10.73 10.36
3,4	25	Felt the same	10	10.59 10.27
5,6	50	A bit harder (not much difference)	9	10.10 10.43
7,8	75	Felt the same	9	9.89 9.96
9,10	100	Felt the same	9	10.40 9.86
11,12	150	A bit more difficult (slower to start off)	7	10.16 10.19
13,14	200	Slower (harder)	6	11.32 10.96
15,16	250	More difficult	5	11.27 11.26
17,18	0	easier	7	10.99 10.66

Comments:
Started experiment with 2 walks without FES. Walking speed: 14.49s, 14.38s

Appendix J: IET conference abstract and presentation

IET Seminar on Antenna and Propagation for Body-Centric Wireless Communications 2009
Abstract Template

Title	Developing a body-centric wireless network solution for systems used to correct movement disorder caused by paralysis
Authors	Choukri A Mecheraoui, Stacey Finn, Rod Lane, Dr Jon Cobb, Prof Ian Swain.
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Abstract: (Your abstract must use Normal style and should not be more than one side in length)	Each year, more than 140,000 cases of stroke are registered in the UK. Of all acute stroke patients, half will be left with impaired use of their limbs. Functional Electrical Stimulation (FES) techniques are well established for improving mobility, function and quality of life of the neurological injured person. Control of FES is usually achieved using body worn pressure sensors, accelerometers or electromyogram sensors. Depending on the extent of the injury and complexity of movement disorder, many sensors and channels of stimulation might be necessary to improve gait or movement. However, this results in a complex multi-channel stimulator which is often rejected by the user due to the size, complexity and cosmesis. These issues can be addressed to some extent by using distributed systems that split the complex function of the multi-channel stimulator into multiple local stimulators around the body. However using conventional techniques this results in a complex network of wires, making it complex and inconvenient for the wearer. The obvious solution is to replace the wires with a wireless network of sensors and stimulators where each node from the network communicates with one or multiple other nodes and small enough to be placed where it needed. Because of the safety implications of this application, any body-centric wireless network of this type must be at least as reliable as a wired system with acceptable latencies. Our research involves choosing the wireless technology that can ensure reliability, short latency and low power consumption in all environments, and investigating the most efficient network topology that performs the best for this application. The work also involves tests on the propagation of waves around the body and antenna performance in different locations. Designing the wireless network with the appropriate characteristics will allow the development of a new generation of FES system that are very convenient for use and expandable so that new sensors or stimulators can be easily added to the network to meet the needs of each individual user.

Full presentation available at:

http://tv.theiet.org/technology/communications/1745.cfm

Appendix K: UKIFESS conference abstract and poster

1st Annual Conference of the International Functional Electrical Stimulation Society (UK and Ireland Chapter)
April 2010 - University of Salford, UK

Sensors for triggering practical Functional Electrical Stimulation walking systems

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1. Introduction

Functional Electrical Stimulation (FES) techniques have shown significant improvement in mobility and functionality to many patients with pathological gait resulting from upper motor neurological injuries such as stroke, Multiple Sclerosis (MS), etc. Effective functioning of FES walking systems relies on accurate and reliable detection of gait events (i.e heel rise and heel strike) which depends on the type of sensors and the detection algorithm used.

2. Aims

The aim of this paper is to review the literature in the field of FES sensors to compare the performances, reliability, and practicality of the different sensing techniques and the detection algorithms associated with them in order to identify the best options available currently for next generation FES walking systems.

3. Methods

A literature search has been performed in the electronic data base PubMed. The review focused on papers reporting gait event detection techniques used for FES walking systems published over the last two decades up to December 2009.

4. Results

The literature search resulted in identifying six types of sensors used for FES walking systems found in 64 papers reviewed; Force Sensing Resistors (FSR), Accelerometers, Gyroscopes, Electromyography (EMG), and Tilt sensors, Electronystagmography (ENG). Kinematic sensors (Accelerometers and Gyroscopes) are found to be the most investigated types of sensors. Also, machine learning techniques were investigated to be combined with detection algorithms.

5. Discussion and Conclusions

FSRs (foot switches) are commonly used in commercial FES walking systems such as the Odstock Stimulator, NESS L300, and the Duo-STIM. FSRs are characterised by the simplicity of their output signal which is in an on/off format. For most patients, FSRs sensors provide reliable performance, however, reliability can be affected by the position of the FSR in the shoe [1] and some gait patterns (eg: shuffling or toe walkers). The alternative is using kinematic sensors which can be placed on the shank or on the thigh of the subject, making the FES systems more cosmetic. The advantage of these sensors is that they can be used to measure joint angles making it possible to identify all gait phases. However, the output signal from this type of sensors is complex and depends on where they are worn, requiring advanced detection algorithms making them more liable to errors [2]. Moreover, reliability differs from one person to another depending on their gait pattern.

Combining different types of sensors might be a logical choice in order to compensate for the disadvantages of each sensor separately; for example, combining a FSR with a kinematic sensor as described in [2] will improve the reliability in different walking conditions and avoids detecting false events such as shifting weight from one side to another. Another approach to improve reliability in different circumstances is by integrating a machine learning technique to learn different gait patterns as suggested in [3] where a neural network was trained on gait data collected from 50 unimpaired subjects. The detection system was reported to be robust and accurate. Such system may require larger processing resources which might raise the cost and power consumption.

This comprehensive literature review has indentified that some of the sensing techniques used in FES systems are reaching maturity and offer high levels of performance and reliability. Furthermore, it is apparent that future development of FES systems will benefit from exploiting the rapid advances in machine learning techniques currently being made in fields such as robotics. Our group is currently developing adaptive systems tailored specifically to address the requirements of the next generation of FES systems.

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Sensors for triggering practical Functional Electrical Stimulation walking systems

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1. Introduction

Functional Electrical Stimulation (FES) techniques have produced significant improvements in mobility and function for many patients with pathological gait resulting from upper motor neurone injuries such as stroke, and Multiple Sclerosis (MS).

Effective functioning of FES walking systems relies on accurate and reliable detection of gait events (e.g. heel rise and heel strike) which depends on the type of sensors and the detection algorithm used.

2. Why triggering is needed in FES

- Stimulation is triggered only when it is needed.
- Effectiveness of the system relies on consistent gait event detection.
- Any missed event might increase the risk of falling and reduces user confidence.
- Increases comfort by avoiding unwanted stimulations.

3. Hand switch controlled FES

Triggering stimulation can be done using a hand switch commanded by the user. The switch can be placed on crutches or on a separate box carried in the hand.

Advantages:

- Simple integration with the stimulator unit to start/stop the stimulation burst.
- No need for detection algorithm.
- Complete control over start and end of stimulation burst by the user.

Disadvantages:

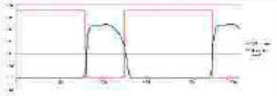
- Requires large amount of concentration (not comfortable, tiring).
- The user needs time to learn synchronising stimulation bursts with stepping to have effective benefits.

4. Footswitches

Footswitches can be Force Sensing Resistors (FSR) that are usually placed under the heel. They are the most used sensors in commercial walking FES products.

Advantages:

- On/off like output format signal resulting in simple detection algorithms.
- The most reliable according to the literature [1].
- Easy to wear.
- Most accurate timing.



FSR sample data associated with triggering signal

Disadvantages:

- No information during the swing phase.
- Mis-trigger when user shuffles or shifts weight from one foot to the other.
- Must wear shoes.
- Limited performance on stairs and toe walker subjects.

6. Kinematic sensors

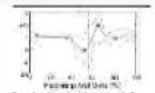
Accelerometers and/or gyroscopes are used to measure acceleration or angular velocity to estimate joint angles or inclination.

Advantages:

- Information about the whole gait period (including swing phase).
- Can be placed on the shank or the thigh, next to the stimulation channel, meaning no wiring is needed.

Disadvantages:

- Less reliability and timing accuracy compared to FSRs.
- Complex detection algorithm.
- Do not work for all pathological gaits.
- Requires calibration.
- More than one sensor is required most of the time.



Foot Accelerometer data sample from unimpaired subjects [2]

7. Combined (FSR and Kinematic)

Combining a kinematic sensor with an FSR:

- Increases reliability (compared to sensors used separately).
- Avoids mis-triggering due to shuffling and weight shifting.
- Kinematic sensor can be accommodated with the stimulator or the FSR.

8. Other sensors

Other types of sensors can be used to detect gait events such as:

- Electromyography (EMG).
- Natural sensors (implant a nerve-cuff electrode around the sensory nerve of the tibial nerve).

These types of sensors have shown poor performance and suffer from noise due to the weakness of the captured signals and the electrical activity in surrounding nerves and muscles.

9. Machine learning techniques

Detection rules are crucial for a reliable detection algorithm. Machine learning techniques can be used to establish them:

- Learn different pathological gaits off-line to be used later in setting up detection rules that works on most unimpaired gaits.
- Learn gait patterns of a specific subject.

Resulting in an increase in reliability and timing accuracy.

10. Conclusions

- FES systems are reaching maturity and offer high levels of performance and reliability.
- FES systems will benefit from exploiting the rapid advances in machine learning techniques to improve gait event detection.

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[2] Lau H, Tong K. The reliability of using accelerometer and gyroscope for gait event identification on persons with dropped foot. Gait Posture. 2008 Feb;27(2):248-57.

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1st Annual Conference of the International Functional Electrical Stimulation Society (UK and Ireland Chapter), 15th & 16th April 2010

Appendix L: EWSN 2011 conference

Poster Abstract: Wireless Network of Local Stimulators and Sensors for People with Neurological Disabilities

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***Abstract*—Neurological lesions can result in weakness/loss of one or multiple limb movement. Functional Electrical Stimulation (FES) is used to improve/regain mobility in some conditions. However, FES users might experience difficulties using these devices due to wires. This work investigates the feasibility of a wireless FES system which consists of a network of sensors and stimulation units.**

I. Introduction

Each year, hundreds of thousands people are affected by a neurological related disease or lesion causing some of them partial or complete dysfunction of one or more limbs. Functional Electrical Stimulation (FES) techniques have shown a significant improvement in mobility and function to many of these neurological patients. FES is an artificial technique of stimulating motor nerves to cause contraction of muscles. Depending on the extent of the injury and complexity of the movement disorder, many sensors and channels of stimulation might be necessary to improve movement. However, this could result in a complex multi-channel stimulator which is often rejected by the user due to the size, complexity and cosmesis. These issues can be addressed to some extent by using distributed systems that split the complex function of the multi-channel stimulator into multiple local stimulators around the body. On the other hand, using conventional techniques will result in a complex network of wires making it difficult and inconvenient for the wearer.

The obvious solution is to replace wires with a wireless network where each node from the network communicates with one or multiple nodes, and is small enough to be placed where needed. As a consequence of the inherent safety implications in this application, any body area wireless network of this type should approach the reliability of the existing wired system and achieve acceptable latencies. This research involves choosing the wireless technology that can ensure reliability, short latency and low power consumption in all environments and conditions, and investigating the most efficient network topology that offers the best performance for this application. In addition, the research will investigate the use of intelligent sensors in order to minimise their number and hence improve the efficiency of the system.

II. Aims

The aim of this poster is to present the research work being done to investigate the feasibility of a wireless network of stimulators and sensors for FES applications. It explains the requirements for the wireless system in terms of reliability, latency, and power consumption. This research will lead to the design of a new generation of FES systems that are convenient for use and expandable so that new sensors or stimulators can be easily added.

This project is motivated by the findings of surveys conducted by Taylor et al. [1] [2] and feedback from clinicians in the National Clinical FES Centre (Salisbury District Hospital, Salisbury, UK). Taylor et al. discuss feedback obtained from patients using the FES system ODFS III (Odstock Medical Ltd, Salisbury, UK). In particular, it was noted that patients had difficulty dressing and undressing while wearing the device. Moreover they found the device occasionally unreliable, which was identified as due to breaking or inadvertent unplugging of wired connections. This suggested that a wireless network between the sensors and the stimulator units would improve overall FES system performance.

III. Methods

A key initial step in the project was to identify the wireless technology to be used as a wireless network. This system had to satisfy the following requirements necessary to be used for FES applications:

A. Wireless requirements

Reliability

Reliability is the most important requirement in this application since it affects directly the safety of the FES device. The reliability of this system should at least approach that of a wired system. Maximising reliability is essential to ensuring patient safety and confidence in any FES system.

Latency

FES devices rely on data from sensors to activate and inhibit stimulation. Therefore, any delay in receiving data from sensors will reflect on stimulation timing. This necessitates that the wireless system needs to have minimum latency.

Power consumption

All nodes in this system are battery powered, therefore low power consumption is essential to give the patient at least one day of battery life. Ideally it would give a battery life of six months which is usually the period between visits to the clinic.

B. Prototype

In order to verify these requirements a prototype wireless FES system was made. There are two types of nodes in this system; sensory node and stimulation node. Sensory nodes use accelerometers, gyroscopes, or pressure sensors to detect events in the gait and/or arm movement of the user. Sensors process data locally and transmit events to one or multiple stimulation nodes, depending on the required information for each stimulation channel. Stimulation nodes make decision on stimulation output depending on the received messages from sensors and/or other stimulation nodes.

A series of experiments were designed to investigate the performances of the wireless system.

This work also involved investigating the possible network topologies best suited to this application. This was done by comparing the advantages and disadvantages of each topology and concluding which is the best compromise in terms of reliability and power consumption.

Each node includes a microcontroller (PIC 18LF14K22, Microchip, USA) and a ZigBee module (ETRX3, Telegesis, UK), and is battery powered.

IV. Results

The available wireless technologies that can be used for this application are discussed by Hoa et al. [3]. ZigBee is designed to be a robust communication system that can handle interference. Moreover, it is designed to be low power and can run on batteries. In addition to this the cost of ZigBee modules is reasonably low. The disadvantage of ZigBee compared to other personal network area networks is the relatively low bit rate of 250kbps (in the 2.4GHz band).

ZigBee can work in different network topology configurations; star, tree, or mesh topologies. Although mesh topology ensures the highest reliability, it results in much higher power consumption than the other configurations. Moreover, if a message is routed through other nodes, it will increase the latency. Star topology on the other hand, favours power consumption since nodes communicate only with the coordinator and do not route any messages. Thus all nodes except the coordinator can be Reduced Function Devices (RFD) which do not require continuous operational power. However, enabling power conservation results in an increased latency compared to the situation where a message is sent directly from one node to another. Tree topology is a compromise between the two. Devices that require communication with multiple nodes can be made Full Function Devices (FFD) and nodes that need to communicate with only one node can be made RFD to save power.

The wireless prototype was tested both in the laboratory and under real world operational conditions to investigate the behaviour of the system. Experiment on the prototype showed high reliability, acceptable latency and power consumption. The findings from these experiments are being analysed.

V. Discussion and Conclusion

ZigBee was chosen to be used for this application as it is the most reliable Personal Area Network (PAN) commercially available and lower in cost. The relatively low bit rate is acceptable due to the nature of this application which does not require streaming data. A proprietary wireless PAN technology could be designed to perform even better for this application by reducing latency and power consumption. However, the aim of this research is not to design a new wireless protocol but adapt a commercially available technology to FES applications.

Although ZigBee uses the 2.4GHz band which is unable to penetrate the human body easily, research by Valdastri et al. [4] showed that using implants communicating via ZigBee modules was feasible.

By comparing the advantages and disadvantages of each network topology that ZigBee can handle, tree topology appears the best configuration for this application. This is due to the flexibility that it offers in terms of the type of device and direction of communication between nodes. For instance, a sensory node can be made RFD and made to communicate to a stimulator node (FFD) that relies on the data from this sensor to apply stimulation. This node can also forward messages received to other stimulator nodes as required.

Initial results of experiments on reliability, latency and power consumption of the wireless prototype are encouraging and show the feasibility of a wireless FES system.

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Wireless Network of Local Stimulators and Sensors for People with Neurological Disabilities

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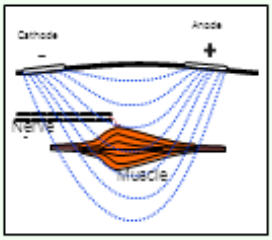
2 Department of Clinical Science and Engineering, Salisbury District Hospital, UK

1. Aims and objectives

- Investigate the feasibility of a wireless network of stimulators and sensors for FES applications.
- Verify the wireless requirement for this application

2. Introduction to FES systems

- Functional Electrical Stimulation (FES) techniques have shown significant improvement in mobility and functionality for many people with neurological injuries such as stroke, and Multiple Sclerosis (MS).
- FES works by electrically stimulating a nerve to cause contraction of muscles.
- Stimulation is triggered based on data from sensors.
- In multi-channel stimulation multiple muscle groups are stimulated.



3. Why wireless FES system?

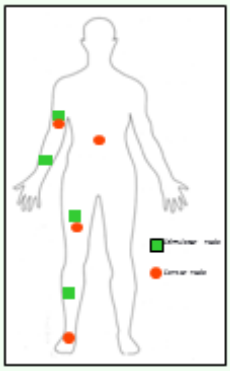
- Patients do not like wires for cosmetic and practical reasons [1-2].
- Wires are subject to wear and tear affecting the reliability of the system.

4. Wireless distributed FES system

- A distributed FES system is composed of multiple stimulator nodes and sensor nodes.
- All nodes can communicate together wirelessly if needed.

Advantages:

- Relatively easy to wear compared to the wired system.
- More acceptable cosmetically.
- No redundant sensors since data can be shared wirelessly.
- Expandable and can be personalised to individual needs



5. Wireless system requirements

- Reliability: Receiving transmitted events reliably is important in this application due to the safety implications.
- Latency: it affects stimulation timing, which reflects on the efficiency of stimulation.
- Power consumption: all nodes are battery powered, therefore it is important to keep consumption low.

6. Chosen wireless technology

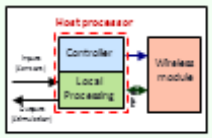
- For this project, only commercially available wireless technologies were considered. (Compared bellow)

	IEEE 802.11 (Wi-Fi)	IEEE 802.15.1 (Bluetooth)	IEEE 802.15.4 (ZigBee)
Battery life (AA)	Hours	Days	Years
Complexity of MAC* and PHY**	High complexity	Complex	Simple
Operating frequency	2.4GHz	2.4GHz	868/915MHz or 2.4GHz
Max bit rate	54 Mbps	3 Mbps	256 kbps
Network size	32 nodes	7 nodes	64000 nodes
Max Range	100m	10m	10 to 100m

Table: Existing Wireless Technologies [3]

- ZigBee appears to be the best suited for this application.

7. Hardware



In every node (stimulator/sensor):

- Host processor.
  - Controls the wireless module.
  - Process data / generate stimulation.
- Wireless module (can be upgraded).

Stimulator node:

- No stimulation output.
- Triggers a sounder instead of the stimulation output.
- Powered with a 9v battery (higher consumption on these nodes)

Sensor node:

- Accommodate one or multiple sensors (accelerometer, pressure sensor, or gyroscope).
- The sensor node is powered with a coin cell battery.

8. Initial results

- Results of experiments are still being analysed.
- Initial data suggest that the system meets the wireless requirements needed for this application.

9. Conclusions

- A wireless FES system will improve the acceptance of multichannel FES systems by patients, and the ease of use.
- ZigBee can be used for this application.
- Initial results of experiments on reliability, latency and power consumption are encouraging.

10. References

[1] Taylor R, Burridge J., Dunkerley, A., Lamb, A., Wood, D., Norton, J., and Swain, I., 1999. Patients perceptions of the odstock dropped foot stimulator (odfs). Clinical Rehabilitation, 13 (5), 439.
[2] Taylor R., Johnson, M., Mann, G., and Swain, I., 2004. Patterns of use and users' perceptions of the odstock dropped foot stimulator following stroke and multiple sclerosis
[3] Hao, Y., Foster R., Cinguist, M., Beghein, N., and Gallee, G., 2008. Wireless body sensor networks for health-monitoring applications. Physiological Measurement, 29 (11), R27-R56

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8th European Conference on Wireless Sensor Networks, Bonn, Germany (23-25/02/2011)

Appendix M: IEEE Radio & Wireless Week 2012 conference

Evaluation of a wireless in-shoe sensor based on ZigBee used for drop foot stimulation

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***Abstract* — External stimulation of the Tibialis anterior muscle is a technique employed to improve mobility for patients with some neurological disabilities causing drop foot. This is achieved by electrically stimulating the motor nerve which causes contraction of the muscle. For functional use the stimulation is applied during periods when the foot needs to be lifted. This period is detected using a sensor usually placed in the shoe of the patient. The stimulation unit is placed distal from the sensor which requires a robust link to ensure a safe and reliable function. A wireless link is a convenient choice especially for users with limited mobility. However, a wireless link is subject to interference that could cause reliability issues and affect latency of transmissions. This paper investigates a wireless link based on ZigBee and estimates the reliability and latency in laboratory conditions with different interference sources. Results are encouraging and showed acceptable performances for such an application. Clinical trials of this system are being undertaken at present.**

***Index Terms* — Dropped Foot Stimulation, Wireless FES, ZigBee, in-shoe sensor.**

I. Introduction

Current Functional Electrical Stimulation (FES) systems are able to generate electrical stimulation to correct for neurological dysfunctions caused by upper motor neurone lesions. FES was first introduced as a functional solution to correct drop foot in 1960, Liberson et al [1] and remains the most widely used application of FES technology. Typically, in drop foot applications a single FES channel is used to correct the inability of dorsiflexing the foot (lifting the foot and decreasing the angle between the foot and the leg), and insufficient eversion (ankle turning outwards). Drop foot stimulation systems have been shown to improve the efficiency of pathological gait and reduce the risk of falling as reported by Burridge et al [2].

Correction of the dysfunction of drop foot requires detecting the principal events of the gait during which the foot is not in contact with the floor. During this period stimulation must be applied to the Peroneal motor nerve which controls the group of muscles responsible for dorsiflexion and eversion of the foot. The start and finish events of the swing phase are usually defined as the period between the time the heel is lifted from the ground (heel rise) and the time the heel returns to the ground (heel strike). Accurate and reliable event detection is crucial for an effective FES system, and therefore sensor technology and detection algorithms have to be designed carefully to achieve optimum performance. A simple Force-Sensing Resistor (FSR) remains the most widespread technique used in current commercial systems [3] since it provides reliable event detection at relatively low cost. However, this requires placement of the sensor in the shoe and typically under the heel. This necessitates a link (wired or wireless) to the stimulation unit which is usually attached to the leg or waist [3]. A wired link can lead to discomfort for the patient and due to prolonged flexing can reduce the operational lifetime of the FES system. On the other hand, a wireless link offer more comfort of use compared to the wired one due to the lack of wires. However, wireless links can be subject to interference causing delayed transmissions and even reliability issues. This paper investigates using a ZigBee network as a medium of communication between the sensor node placed in the shoe and the stimulation unit. A series of experiments were conducted to estimate the reliability and latency of the system with the main sources of interference in the 2.4GHz band used by ZigBee. These experiments are a precursor to a clinical trial of the wireless in-shoe sensor with patients who are currently using the wired system.

II. Methods

The experiments were performed in laboratory conditions. This allowed controlled levels and type of interference which helped identifying the worst scenarios. Each experiment lasted for about 10,000 transmissions and were repeated with the main sources of interference (Wi-Fi, Bluetooth, ZigBee, and Microwave ovens).

Both the sensor and stimulation nodes integrate a ZigBee module (ETRX3, Telegesis, UK) and a microcontroller (PIC, Microchip, USA). In the sensor node, the microcontroller is fed with a square wave, similar to the signal given by a FSR worn in the shoe, while walking. The frequency of the square wave was about 1.17Hz that matches a fast walking pace. The sensor node transmits only the corresponding event every time the heel events algorithm, run on the microcontroller, detects heel rise or heel strike. In this experiment, they

correspond to rising edge and falling edge of the square wave.

The two nodes have a digital output which represents detection of events (heel rise and heel strike) in the sensor node, and reception of the corresponding event in the stimulation node, which translates into stimulation on and off. Comparing the two signals is used to estimate the reliability and latency of transmission.

A. Interference free experiment

First the system was tested in ideal conditions by choosing a quiet ZigBee channel. The sensor node was put on an insole on the floor underneath a desk, and the stimulator was left on top of the desk. This arrangement was the closest, achieved in the laboratory, to how the device will be worn; sensor in the shoe and stimulator attached to the waist.

B. Wi-Fi interference

This experiment is designed to create a Wi-Fi network that overlaps with the ZigBee channel used. The Wi-Fi network was created using an IEEE 802.11b router (DWL-900AP+, D-Link) set to stream data to a laptop (Satellite Pro A330, Toshiba). The Wi-Fi channel chosen was Wi-Fi 3 which coexists with ZigBee channel 14 set on the experimental system. The data rate to and from the laptop was recorded using NetWorx (V 5.1.7). The experiment was repeated 12 times with different arrangements of the ZigBee nodes and the Wi-Fi router each time. This was done by moving the Wi-Fi router to a new location every trial; starting from few meters away from the ZigBee system, to few centimetres from the sensor node and then few centimetres from the stimulator node. The spectrum activity of the 2.4GHz band was recorded using a spectrum analyser (Wi-Spy 2.4x, MetGeek, USA) placed next to the ZigBee module on the stimulator node.

C. Bluetooth interference

Bluetooth interference was created by streaming audio from a tablet PC (Archos 70) via Bluetooth to a laptop with a Bluetooth dongle (ACB10EU, Targus). The experiment was repeated three times to test different locations of the Bluetooth source related to the two nodes of the FES system. The spectrum activity of the 2.4GHz was recorded using the spectrum analyser.

D. ZigBee interference

The system was tested with another ZigBee network that uses the same frequency channel (ZigBee 14). The second network was composed of two Telegesis development boards (ETRX3DVK). One of these boards was set to request reading a register on the second node periodically every 250ms. This resulted in two transmissions (one from each node) every 250ms. Transmission power on both nodes was set to maximum to cause the highest interference possible with this system. The experiment was repeated four times with different arrangements of the two nodes. As with the previous experiments, the spectrum activity was recorded.

E. Microwave oven interference

Microwave ovens which operate in the 2.4GHz band are very likely to be found in environments where the system will be used. This experiment is designed to test estimate the reliability and latency of the system while operating next to a microwave oven (CE107B, Samsung). Two trials were performed in this experiment each lasting for five minutes allowing a total of 780 transmissions (could not reach 10,000 transmissions due to some practical issues). The microwave oven was set to full power in both trials and a glass of water was used as a heating load.

F. Effect of loaded stimulation output

In the stimulator node, the wireless module is located next to a transformer used in the stimulation output stage. Therefore, to ensure that this does not affect the performance of the wireless link, the system was tested while the stimulator generates stimulation output on a load. The stimulation parameters were set to typical values recommended by clinicians in the National Clinical FES Centre (Salisbury District Hospital, UK).

TABLE I
SUMMARY OF EXPERIMENTAL RESULTS

Source of Interference	Number of transmissions	Reliability of transmissions	Number of Failed transmissions	Median latency (ms)	Average latency (ms)	Maximum latency (ms)
Interference free	10091	100%	0	12	12.411	34
Wi-Fi	10517	99.66%	36	13.5	18.355	250.5
Bluetooth	10587	99.91%	10	13.5	19.516	247.5
ZigBee	10619	99.98 %	2	12	12.443	71.5
Microwave Oven	781	99.74%	2	15.5	20.789	88
Stimulation load	11567	100%	0	12	12.26	31

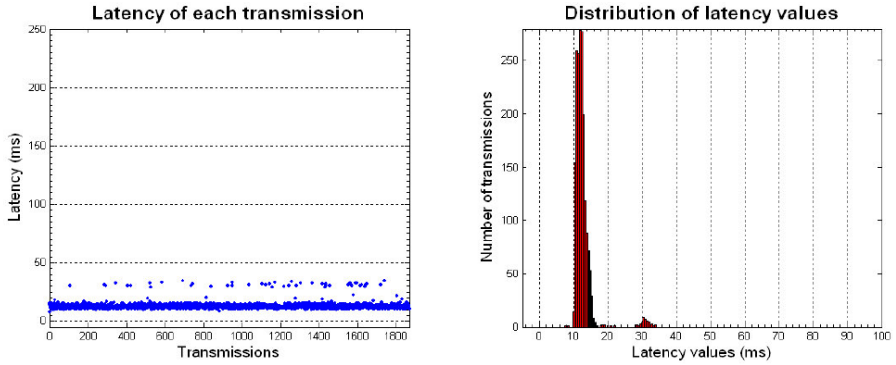

Fig. 1. Latency of transmissions and distribution of latency values from the Interference free experiment

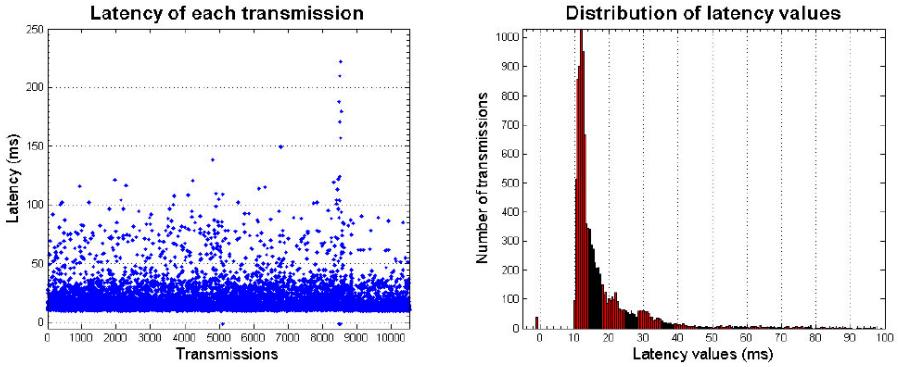

Fig. 2. Latency of transmissions and distribution of latency values from the Wi-Fi experiment (trial 12)

III. RESULTS

The collected data was processed using MatLab to estimate the reliability of transmissions, and to plot graphs of latency values of each transmission and the distribution of these values. Table 1 represents a summary of the results of one trial from each experiment. These trials are the ones showing the lowest performance. The interference levels and duty cycles were measured at the stimulator node using Wi-Spy 2.4x (MetaGeek). Table 2 summarises these values from the trials represented in table 1.

Interference free and loaded stimulation experiments showed the best performance with no failed transmissions and all were received within 34ms. Graphs of Latency values and distribution from the interference free experiment are given in Fig 1.

The lowest performance was noticed with the Wi-Fi interference experiment. Fig. 2. represents these results which are from the trial where the router is located between the two ZigBee nodes on the same table (30cm from each node). In this trial the data rate in the Wi-Fi network was an average of 118kByte/s (in) and 4.06kByte/s (out) with a maximum of 252kByte/s. The MatLab function created for this occasion was set to give a negative latency value "-1" for failed transmissions. This explains the negative latencies found in the graphs. It is also noticeable that when the experiment reached around 8500 transmissions, 34 transmissions were not received

TABLE II
SUMMARY OF INTERFERENCE LEVELS AND DUTY CYCLES IN THE USED ZIGBEE CHANNEL MEASURED AT THE RECEIVER (STIMULATOR) NODE

Source of Interference	Average levels (dBm)	Maximum levels (dBm)	Duty cycle (%)
Wi-Fi	-50.7	-34.0	2.73
Bluetooth	-68.5	-38.0	0.17
ZigBee	-52.6	-23.5	0.49
Microwave Oven	-41.1	-15.0	0.40

and few transmissions recorded the highest latency values of the experiment. Although the traffic on the Wi-Fi network was fixed, this might be caused by accumulation of transmission errors which required sudden retransmissions within that period. This resulted in overloading the channel and increasing the duty cycle of the Wi-Fi network.

IV. DISCUSSION

The experiments in the laboratory environment were designed to test the system in most challenging conditions with the most likely sources of interference in everyday use. Repeating experiment in different arrangements helped identifying the worst performance with each source of interference. For instance the Wi-Fi interference experiment was repeated 12 times to ensure that the system is tested under worst case conditions.

The results showed that Wi-Fi was the strongest source of interference to the system in certain arrangements. Placing the router between the two nodes while transferring data at high rate (>100kByte/s) resulted in the lowest reliability (99.66%) of all the experiments. It also resulted in higher transmission latencies. However, this arrangement of nodes and Wi-Fi router does not last for long periods since the user is moving and the router is most of the time fixed. Furthermore, performance does improve the further the router is, as found by these experiments. Therefore the performance of the system is acceptable since reliability will be approaching 100%. This is thanks to the ability of ZigBee to coexist with Wi-Fi even when exposed to high levels of interference. This can be explained by the fact that ZigBee uses an anti collusion mechanism known as Carrier Sense Multiple Access with Collusion Avoidance (CSMA-CA) [4] which waits for a quiet period to transmit. Moreover, Wi-Fi does not reach 100% duty cycle within one ZigBee channel allowing time for the ZigBee device to transmit successfully. However, as a result of CSMA-CA, transmissions can experience increased latencies as found in the results above.

The high values of transmission latency could have an effect on the effectiveness of stimulation and could affect the safety of the patient. A study is designed to investigate these effects by applying delayed stimulation on a FES user and record walking patterns using motion analysis laboratory to be analysed by clinicians. This study will help identifying what are the accepted latencies and what effects they could have on the walking patterns. However, although two of the transmission latencies were over 200ms, as seen from the results, over 96% of transmissions are received within 50ms and over 99% are within 100ms, even when exposed to the highest levels of interference.

V. CONCLUSION

In conclusion, the proposed wireless sensor will benefit users from the fact that there is no need to handle wires and avoids wear and tear of wires. Interference, mainly Wi-Fi networks, can pose issues of reliability and latency to the ZigBee network. However, as explained earlier, the conditions that can cause some transmission failure and large transmission delays are not likely to be experienced for extended periods. Moreover, a study will take place to investigate the clinical effect of delays on the FES system. Performance of the wireless link can be better in real world conditions since exposure to high levels of interference is not likely in the environments where the drop foot stimulator is usually used.

The results of these experiments reported here show that the system is safe to be tested with patients in real world conditions. The next stage is therefore to conduct a clinical trial of the wireless system which is being undertaken at present.

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Evaluation of a Wireless in-shoe Sensor Based on ZigBee used for Drop Foot Stimulation

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1. Aims and objectives

- To estimate the reliability and latency of a wireless sensor for Drop Foot Stimulation based on ZigBee.

2. Introduction to Drop Foot Stimulation

- Drop Foot Stimulation is an artificial technique of stimulating the tibialis anterior (Tib. Ant) muscle to improve walking for many people with neurological injuries such as stroke, and Multiple Sclerosis (MS).

Fig 1. ODFS Pace [3]

- Muscle contraction is achieved by electrically stimulating the motor nerve of Tib. Ant.
- Stimulation is triggered based on data from an in-shoe sensor.
- Sensor leads are reported to cause reliability issues [1] and are considered by some patients impractical and cosmetically unacceptable [2].

Proposed Solution:

- A wireless in-shoe sensor placed in an insole with a wireless interface for the stimulator.
- For safety implications, the wireless system must be reliable with low latency.

3. Prototype

- Prototype consists of two nodes; stimulator and sensor.

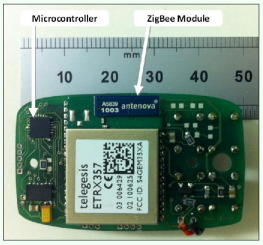

Fig 2. Prototype node

Both nodes (Fig 2) include:

- Microcontroller.
  - Controls the wireless module.
  - Processes data from sensor.
  - Generates stimulation trigger used in the stimulator.
- Wireless module (ZigBee).
- Digital output represents whether the foot is lifted and is used to estimate reliability and latency.

4. Experiments

- All experiments were in laboratory environment and lasted for about 10,000 transmissions (Tx).
- Interference sources tested were: Wi-Fi, Bluetooth, ZigBee, a Microwave oven, and loaded stimulation (Noise from output stage).
- Sensor replaced with a square wave (1.17Hz) -> similar to sensor data when walking.

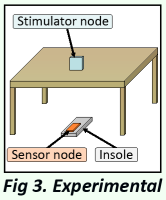

Fig 3. Experimental setup

5. Results

- 23 combined trials were performed overall.
- Table 1 summarises results of one trial (with the lowest performance) from each experiment (one source of interference).

Source of Interference	Number of events (Tx)	Reliability of Tx	Number of missed events	Median latency (ms)	Average latency (ms)	Maximum latency (ms)
Interference free	10,091	100%	0	12	12.411	34
Wi-Fi	10,517	99.66%	36	13.5	18.355	250.5
Bluetooth	10,587	99.91%	10	13.5	19.516	247.5
ZigBee	10,619	99.98 %	2	12	12.443	71.5
Microwave Oven	781	99.74%	2	15.5	20.789	88
Stimulation load	11,567	100%	0	12	12.26	31

Table 1. Summary of experimental results

- Wi-Fi was the strongest source of interference.

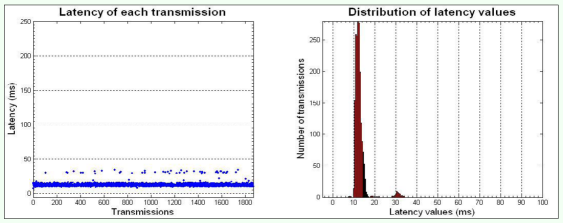

Fig 4. Latency representation – Interference free

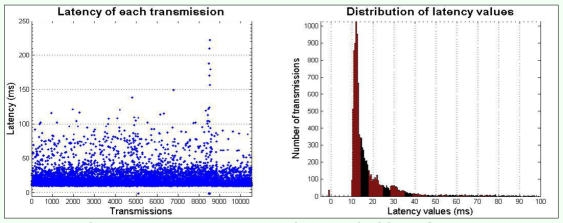

Fig 5. Latency representation – Wi-Fi interference

6. Conclusions

- Wi-Fi could cause reliability to drop to 99.66%.
- Latency was affected by Interference and reached a maximum of 250ms on one occasion. However, over 99.32% of transmissions were received within 100ms.
- Performance is acceptable and encouraging for a real life application which will benefit users.
- A clinical trial of the system is being undertaken.

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Appendix N: Stimulation output test report

Output Test of Software CM_11727

Document Control

Document Issue Information – Please use and refer to this document from the internal NPD website server. It is located on 'companyweb/NPD/POML001/6. Trialling and System Testing'. Please also refer to the document change database on the server.

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Final Sign-off	Signed	Acceptance	Date
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Project – Choukri Mecheraoui PhD

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14/12/2011	DN	1	Issue 1	Yes

DCD: Document Control Database

Introduction

A short test to ensure that the minor modifications to software code CM_11727 have not resulted in an adverse stimulation output. The testing was performed by D.Nolan on behalf of C.Mecheraoui. ODFS® Pace stimulator SN2426 P79 was used for the test. The device was powered by a LiPo iPower US PP3 rechargeable battery.

Test Results

Set Current @ 50% Pulse Width (default setup)	Measured Voltage (V)	% Error
15	13.9	-7.3%
20	19.7	-1.5%
25	25.2	0.8%
30	30.0	0%
35	35.5	1.4%
40	41.0	2.5%
50	51.2	2.4%
60	60.4	0.7%
70	71.6	2.3%
80	81.1	1.4%
90	90.6	6.7%
100	103.4	3.4%

Set Pulse Width (%,µs – default setup, 30mA)	Measured Width (µs)	% Error
10%, 36	35	-2.8%
20%, 72	73.4	1.9%
30%, 108	113	4.6%
40%, 144	153	6.3%
50%, 180	194	7.8%
60%, 216	234	8.3%
70%, 252	273	8.3%
80%, 288	314	9.0%
90%, 324	354	9.3%
100%, 360	362	0.6%

Time Out (ms), 0ms ramps and extension, 30mA	Measured Time (ms)	% Error
300	306	2.0%
400	407	1.8%
500	505	1.0%
1000	1015	1.5%
1500	1518	1.2%
2000	2024	1.2%
2500	2527	1.1%
3000	3037	1.2%
3500	3543	1.2%
4000	4049	1.2%
4500	4556	1.2%

Extension (ms), 0 ramps & 1000ms timeout, 30mA	Measured Time (ms)	% Error
0	0	0%
50	49	-2.0%
100	103	3.0%
200	201	0.5%
300	306	2.0%
400	404	1.0%
500	505	1.0%
1000	1011	1.1%
1500	1517	1.1%
2000	2027	1.4%

Conclusion

All outputs within specification ±10%.